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FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE REFORM ACT OF 1988

MAY 13 (legislative day, MAY 9), 1988.—Ordered to be printed

Mr. LEAHY, from the Committee on Agriculture, Nutrition, and Forestry, submitted the following

REPORT

together with

ADDITIONAL VIEWS

[To accompany S. 1516]

The Committee on Agriculture, Nutrition, and Forestry, to which was referred the bill (S. 1516) having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill as amended do pass.

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BRIEF EXPLANATION

S. 1516, as reported by the Committee, amends the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to improve the pesticide approval process, strengthen provisions that protect public health and the environment, provide a more efficient and equitable

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regulatory program for producers and users of pesticides, and reduce the cost of the pesticide program to taxpayers and the Federal government.

The major provisions of the bill include—

Reregistration.—The Environmental Protection Agency (EPA) would be provided with the funds necessary to complete within nine years the reregistration (review of contemporary data on health and environmental effects) of approximately 600 pesticide active ingredients approved for use prior to 1984. Under current law, GAO estimates that the reregistration process will take at least 36 years and thus not be completed until 2024.

The cost of accelerating the reregistration process is estimated to be $260 million. Approximately $150 million would be paid by pesticide registrants through a one-time reregistration fee based on active ingredients and a modest annual registration maintenance fee that would be charged for nine years. The remaining $110 million would be covered by appropriations.

Indemnification.—Farmers and other end users would be eligible for indemnification for losses they suffer on stocks of pesticides that cannot be used due to suspension and cancellation of a registration. The funds to make indemnification payments would come from the Judgment Fund of the United States. EPA could not make an indemnity payment to any other party for losses on a suspended and canceled pesticide unless a specific line item appropriation of funds is made by Congress in advance for such payment. The bill also provides for reimbursement arrangements among manufacturers, distributors, and dealers. If the Administrator determines that reimbursement for a loss incurred cannot be made due to the bankruptcy or insolvency of the seller, the dealer or distributor suffering the loss would be indemnified through the Judgment Fund.

(NOTE.—EPA may issue a notice of intent to cancel a pesticide registration if information indicates that the product presents an unreasonable risk of adverse effects on human health or the environment. The EPA proposal to cancel may be challenged by the pesticide registrant and other affected groups, and use of the product is allowed until the cancellation proceeding is completed. EPA may suspend the registration of a pesticide if the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation. If EPA suspends the registration, use of the product is forbidden while the cancellation process is conducted.)

Storage and disposal.—The bill would transfer the responsibility for transporting, storing, and disposing of suspended and canceled pesticides from EPA to the pesticide registrant. EPA would share a portion of the storage costs, and would be authorized to order product recalls.

Ground water.—The bill would add new sections to FIFRA and the Safe Drinking Water Act to provide for regulation of pesticide contamination of ground water. The new section of FIFRA would include provisions for determinations by the Administrator as to whether a pesticide has the potential for leaching into ground water, notification of pesticide detections, ground water monitoring by registrants, registration amendments based on the pesticide de-

tections in drinking water wells, and site-specific response to the presence of excessive levels of pesticides in drinking water wells. The new section of the Safe Drinking Water Act would provide for standards for pesticides in ground water.

Farmer liability.—The bill would provide that an agricultural producer may not be held liable under Federal environmental laws for the release or threatened release of pesticide into the environment or for damages incurred from such a release if, as certified by the producer to the Administrator, the application was in compliance with labeling instructions and applicable law. Certification would include a statement of the date of application, name of the pesticide, rate of application, and location of application. The exemption would not apply if the producer acted negligently, recklessly, or with the intent to misuse the pesticide.

Exports/imports.—The bill would add prerequisites for the export of a pesticide that is classified for restricted use, canceled, suspended, or not registered for any use. Notification explaining the pesticide's status and acknowledgement of receipt of such notification would be required prior to the first shipment each year to the person importing the product and an appropriate regulatory official in that country. The Administrator would have to determine that such country has an existing and effective pesticide regulatory program. The bill also includes provisions that would require FDA to enter into cooperative agreements with governments of countries that are major importers of food to the United States, establish computerized data management systems for pesticide residue monitoring, and develop a plan for research needed to improve pesticide detection methods.

Patent term restoration.—The bill would grant patent term extension with respect to certain pesticide, chemical, and plant products that undergo lengthy regulatory review prior to commercial marketing. A patent could be extended for up to five years based on the period that the patented product was subject to a statutorily-mandated review prior to commercial marketing or use. Patent extension would not be available if the patent had previously been extended under this authority, or if the patent was already expired. If a regulatory review began before the date of enactment of the bill, the period of patent extension could not exceed two years.

During the last two years of a patent on a registered pesticide, potential registrants would be allowed to conduct testing, subject to certain exceptions, reasonably related to the development and submission of data to meet regulatory requirements.

Revocation of tolerances.—The bill would require that when a pesticide registration is canceled, withdrawn, or suspended, due to dietary risks to humans, the Administrator would have 60 days to withdraw the tolerances for residues of the pesticide, or any exemption from the need for a tolerance. During reregistration, tolerances or exemptions would have to be reassessed and could be amended or revoked as necessary.

Special review.—The bill would clarify the procedures EPA follows when initiating and conducting a public interim administrative review (special review), and streamline the legal process for cancellation of a pesticide registration following such a review. Reviews would have to be completed within 18 months; cancellation

proceedings that follow such reviews would have to be completed in 10 months. Cancellation proceedings not preceded by a public interim administrative review would be required to be completed within 18 months, unless the period is extended by the Administrator under extraordinary circumstances for no more than one year. Currently the administrative review or cancellation process typically takes five to ten years or more to be completed.

Data coordination.—The bill would require EPA and States to "coordinate and synchronize" tests requested to be conducted by pesticide registrants. The requirement includes a proviso stating that it would not be interpreted as adversely affecting the authority of States to test, regulate, or otherwise control the use of pesticides.

Certification and training.—Requirements for certification and training of commercial and private applicators would be made more stringent, particularly with regard to the use of restricted pesticides. Commercial applicators would be required to undergo refresher training. EPA would be required to develop updated training material.

Inert ingredients.—The bill would direct the Administrator to establish a priority list of 50–75 inert ingredients (chemicals used to dilute or deliver the pest killing agent), and within one year make a determination whether health and safety data are needed with respect to these chemicals. Over time, approximately 1200 inert ingredients presently used in pesticide formulations would be reviewed. EPA could require pesticide labels to include the names of certain inert ingredients due to the hazard which may be posed by the use pattern and concentration level of the compound. In addition, pesticide labels would be required to identify, by notation, the names of any ingredients determined by the Administrator to be inert in the pesticide, but that are active ingredients in any other registered pesticides.

Background

Federal regulation of pesticides began in 1910 with passage of the Insecticides Act (36 Stat. 331). The Act, administered by the U.S. Department of Agriculture, prohibited the manufacture, sale, or transportation of misbranded or adulterated insecticides and fungicides. The purpose of the Act was to protect farmers and consumers against fraudulent products.

In 1947, the Insecticides Act was repealed and replaced with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (61 Stat. 163–172). Under the 1947 Act, Congress imposed a new requirement of "registration" of chemical pesticides prior to their sale or movement in interstate or foreign commerce. However, if the Department of Agriculture denied a request for a registration, the manufacturer could lodge a formal "protest" which the Department and proceed to sell the chemical. The Act further required the prominent display of poison warnings on labels of highly toxic pesticides; the inclusion of warning statements on the label to prevent injury to people, animals, and plants; and the inclusion of instructions for use to provide adequate protection for the public.

Pesticide regulation was expanded further in 1954 by an amendment to the Food, Drug and Cosmetic Act authorizing the Administrator of the Food and Drug Administration to set tolerance limits (or maximum amounts) for residues of pesticides on raw agricultural commodities. The registrant of a pesticide is required to provide data on the level of residue remaining in or on a food crop after pesticide application, as well as scientific data on the toxicity of the chemical. From these data and its own research, the Food and Drug Administration sets a tolerance for residue that may legally remain in or on the food crop when it is marketed. In 1958, the Food, Drug and Cosmetic Act was further amended to prohibit tolerances for residues of carcinogenic pesticides on processed foods.

In 1959 FIFRA was again amended (P.L. 86-139) to regulate several new types of agricultural chemicals such as nematocides, defoliants, desiccants, and plant regulators.

In the early 1960's, increasing public concern about long-term health and ecological effects of some pesticides led to the creation of a Presidential Scientific Advisory Committee to study and report on the issue. In response to the committee's report, FIFRA was amended in 1964 (P.L. 88-305) to eliminate the "protest registration" that permitted a manufacturer to market a pesticide despite the Department of Agriculture's refusal to register it. Differences between a manufacturer and the Department regarding a registration were to be resolved through a hearing or a scientific review committee. The Act was further amended to permit the Secretary of Agriculture to require each pesticide to carry a registration number. The 1964 amendments also provided the Secretary of Agriculture with authority to suspend the registration of a pesticide found to be unsafe, thereby immediately halting its sale in interstate commerce.

When the Environmental Protection Agency (EPA) was created in 1970, authority to implement FIFRA was transferred from the Department of Agriculture to the EPA, and authority to set pesticide residue tolerances (but not to enforce them) was transferred from the Food and Drug Administration to the EPA.

FIFRA was considerably revised in scope and procedure by the enactment of the Federal Environmental Pesticide Control Act of 1972 (P.L. 92-516). The 1972 Act mandated a review of all pesticides registered up to that time in order to reassess the safety of continued use of those products. The "reregistration" was to be completed by 1975. The legislation also provided for direct control over pesticide use, classification of certain products into a restricted use category, registration of manufacturing plants, and a national monitoring program for pesticide residues. It also added environmental effects to the risks to be weighed in the registration process.

The 1972 amendments proved difficult for the Agency to implement from the start. The Federal Pesticide Act of 1978 (P.L. 95-396) was an attempt to overcome implementation obstacles and other problems arising from the 1972 amendments. The 1978 Act expedited the registration process by providing for reregistration on the basis of the generic chemical (i.e., active ingredient), allowing conditional registration, and developing limited data requirements for minor use pesticides. The legislation provided the devel-

oper of a new pesticide with ten years of exclusive use of the data supporting the registration of the new product. In addition, States were given primary enforcement responsibility for the Act. The 1978 Act required the Agency to obtain guidance from its Scientific Advisory Panel on risk assessment analyses that lead to decisions by the Administrator.

Purpose and Need

The purpose of S. 1516, as reported by the Committee, is to strengthen the protection of public health and the environment; restore public confidence that pesticides are approved and used in a manner that meets contemporary health and safety standards; ensure that affordable and effective products are available to pesticide users; and to extend the authorization for appropriations for the pesticide program under the Federal Insecticide, Fungicide, and Rodenticide Act through September 30, 1992.

Pesticide law reform is long overdue. Recently, the General Accounting Office, the National Academy of Sciences, and several Congressional committees have reported on the inadequacy of and contradictions within current law.

In the 99th Congress, both the Senate and the House of Representatives passed comprehensive bills to amend FIFRA, but the differences between the bills were not resolved before the Congress adjourned. Both bills were based to a large extent on a landmark agreement reached after years of negotiation by the Campaign for Pesticide Reform, comprising 41 environmental, consumer, and labor organizations, and the National Agricultural Chemical Association, representing some 92 pesticide manufacturers. S. 1516 builds on many important provisions of that legislation.

REREGISTRATION

At the heart of the problems arising under present law is the pesticide product reregistration program. The 1972 FIFRA amendments ordered the Environmental Protection Agency to reassess the health and safety data on all then-registered products, and continued the requirement that all registrations be renewed every 5 years. Reregistration was to be completed by 1975, but after a brief extension, the deadline was dropped in 1978. Inadequate resources and the sheer magnitude of the task have impeded the Agency's efforts to carry out the reregistration mandate.

As part of its current reregistration efforts, EPA is developing "registration standards" for approximately 600 pesticide active ingredients. Development of these standards entails a review of the data on each active ingredient to determine the adequacy of existing data and the need to require registrants to undertake studies to replace missing or inadequate data. Presently, EPA develops about 25 interim standards per year. To date, 167 interim registration standards have been issued.

Only 40 final registration standards have been issued. According to the General Accounting Office, these final standards may cost as much to develop, in both time and resources, as the interim standards. In the fifteen years since Congress ordered the EPA to carry

out a reregistration program, only two active ingredients have been completely reviewed and formally reregistered.

Concern about the inadequacy of data that support current registrations fuels the controversy surrounding pesticide use. Such concern, in turn, reinforces the desire by States and their political subdivisions to seek increased control over pesticide use; leads to demands for reform of EPA's special review and cancellation process; prompts calls for more stringent protections for workers exposed to pesticides; and increases the effort to limit pesticide use. Consequently, the polarized public debate that surrounds pesticide use cannot be expected to a subside until a successful reregistration program is carried out and restores confidence in the regulatory system that governs pesticide approval and use.

As such, an accelerated reregistration program is the centerpiece of S. 1516. Under the bill, reregistration will be carried out in five phases over the course of nine years and funded largely through fees charged to registrants of pesticide active ingredience and products.

INDEMNIFICATION

Under FIFRA, the Environmental Protection agency is required to idemnify all holders of pesticide products that are suspended and canceled as a result of a determination that the use of such pesticide will create an imminent hazard. Persons covered by indemnification include farmers, commercial applicators, pesticide formulators, pesticide dealers and distributors, and registrants. Indemnification has been a significant drain on the Agency's resources. To date, the Agency has spent over $20 million for indemnity payments for two suspended and canceled chemicals, 2, 4, 5-TP/Silvex and ethylene dibromide (EDM). With an annual operating budget of only $40 million, this obligation has put considerable strain on the Agency's resources. A third chemical, dinoseb, was suspended in October 1986 and canceled. The Agency estimates indemnification costs for this chemical to be $40 million.

To prevent indemnification payments for dinoseb from draining the Agency's fiscal year 1988 budget, Congress ordered in the FY 1988 Continuing Appropriations Act (P.L. 100-202) that indemnification claims be paid from the Judgment Fund of the Treasury rather than EPA's operating budget.

S. 1516 would prohibit the EPA Administrator from making an indemnification payment to anyone other than an end user unless Congress made a line-item advance appropriation. End users, such as farmers and applicators, would continue to be eligible for indemnification through the Judgment Fund. S. 1516 also would provide for reimbursement arrangements among manufacturers, distributors, and dealers. If the Administrator determines that such an arrangement could not be carried out due to a business insolvency or bankruptcy, dealers and/or distributors would be indemnified through the Judgment Fund.

STORAGE AND DISPOSAL

Under the current provisions of FIFRA, the Environmental Protection Agency is responsible for receiving, storing, and ultimately

disposing of pesticides that are suspended and canceled. EPA projects that the storage and disposal costs for the three suspended and canceled chemicals previously mentioned could be as high as $196 million. To meet initial costs being incurred for these purposes, EPA has diverted funds otherwise allocated to the reregistration process.

S. 1516 would change EPA's present role from being responsible for storage and disposal to being the regulator of the process. The responsibility for transporting, storing, and disposing of suspended and canceled pesticides would be transferred from EPA to the pesticide registrant. The registrants have the greatest knowledge of how to handle the chemicals safely and possess the technical expertise and the funds to deal with the products under Agency oversight. The Agency would share a small portion of the storage costs and would be authorized to order product recalls. The amendment is designed to provide incentives to both manufacturers and the EPA so that safe disposal can occur as expeditiously as possible.

GROUND WATER

Ground water supplies drinking water to over 50 percent of the U.S. population, through about 48,000 community water systems and 12 million individual wells. Approximately 95 percent of rural households rely on ground water for drinking, agricultural production, and other uses.

It is only in the last decade—after the 1979 detection of the pesticide aldicarb in ground water on Long Island—that scientists discovered that chemical degradation and the natural filtering action of the soil do not prevent certain pesticides under certain conditions from reaching ground water. The Environmental Protection Agency reports that 19 pesticides have been detected in the ground water of 24 States as of 1984. The contamination is believed to be the result of routine agricultural application of chemicals. In several instances, the level of contamination posed potentially significant health concerns. In the case of the pesticide dibromochloropropane (DBCP), such concern led in part to the cancellation of its uses. In the case of ethylene dibromide (EDB), there was sufficient concern to immediately suspend uses of the pesticide shown to pose a ground water contamination threat.

The Agency has received and is reviewing a number of reports of detections of pesticides in ground water. In order to determine the extent of the problem, EPA has initiated a comprehensive statistically-based survey of drinking water wells across the United States.

States and localities have exercised primary responsiblitity for protecting and managing ground water. Ground water quality management and protection programs at such levels have varied greatly in their approaches and strategies. Many States have adopted specific legislation, policy statements, and regulatory programs. However, there still remains a need on the Federal level to address specifically the regulation of pesticide use with respect to ground water.

S. 1516 would add a new section to FIFRA and would amend the Safe Drinking Water Act to provide for regulation of pesticide contamination of ground water. The new section of FIFRA would in-

clude provisions for determination by the Administration as to whether a pesticide has the potential for leaching into ground water, notification of pesticide detections, ground water monitoring by registrants, registration amendments based on pesticide detections in drinking water wells, and site-specific response to the presence of excessive levels of pesticides in drinking water wells.

COMMITTEE CONSIDERATION

APRIL 29, 1987, HEARING

On Thursday, April 29, 1987, the Committee on Agriculture, Nutrition, and Forestry met to hear testimony on pesticide contamination on ground water.

The first witness was Dr. John A. Moore, Assistant Administrator, Office of Pesticides and Toxic Substances, U.S. Environmental Protection Agency. Dr. Moore highlighted the Agency's progress in building a database on pesticides that may leach into ground water, and outlined the features of EPA's strategy for managing this environmental concern.

EPA has initiated a national survey of pesticides in drinking water wells to establish the frequency and concentration of pesticides in drinking water wells, as well as to examine the relationships among the presence of contaminants, the vulnerability of ground water, and the patterns of pesticide use in the surrounding areas. The survey will examine a total of 1500 drinking water wells for 70 pesticides and 90 other chemicals. The study is presently in the pilot phase in Mississippi, California, and Minnesota, Dr. Moore stated.

Dr. Moore noted that leaching potential is taken into consideration at the time of registration or reregistration. The Agency is in the process of developing a ground water protection strategy, which is expected to be released in May 1988. [Note: the Pesticides in Ground Water Strategy was released in December 1987.] He stated that prevention is the key to a ground water strategy. Dr. Moore expressed the need for specific management plans for particular pesticide threats to ground water and reference points to serve as objective measures to evaluate the effectiveness of the management plans. The Agency intends to use the maximum contaminant levels under the Safe Drinking Water Act as the reference point. When such a level does not exist, the Agency will use standard risk assessment procedures to establish an interim reference point.

Dr. Moore stated that it is the basic policy of the Agency that States should have a dominant role in the management of their own ground water resources. However, the Agency intends to work with the States in development of these management plans. Since 1985, EPA has provided some $20 million in grants to States to develop protection programs.

Dr. Moore concluded by saying that the Agency must take a preventative approach, have a point of reference to gauge the success of the management plan, and tailor the plan to local circumstances.

The next witness was Dr. George Hallberg, Environmental Geologist, Iowa Department of Natural Resources. Dr. Hallberg noted that Minnesota and Iowa have done intensive monitoring and

found that 33–38% of all wells sampled showed pesticide residues. Nineteen different pesticides were identified. In susceptible rural areas, 70–90 percent of farm wells contained pesticides. About 20–25 percent of all the wells have had detections of multiple residues. The large majority of detections tend to occur with elevated concentration of nitrates. Point source problems are more prevalent than previously thought, he said.

Dr. Hallberg stated that contamination is most prevalent in the shallow part of the ground water system, which is in part a function of time. If contamination persists, as evidence is beginning to show, it will be transmitted to deeper ground water. Ground water and surface water are interrelated. Moreover, some surface water studies show that most treatment programs are not removing pesticides.

There is a need for a better database on pesticide usage and for independent research especially in the area of health and environmental epidemiological studies, according to Dr. Hallberg.

Dr. Hallberg cited opinion polls and surveys in which 89 percent of farmers and farm families said that they were very concerned about ground water issues and that more needs to be done about ground water protection. Sixty-five percent said that they were in favor of tighter restrictions on pesticides. Fifty-two percent were in favor of tighter restrictions on fertilizers.

Dr. Hallberg concluded by saying that to fully resolve some of these problems, policies for production, soil conservation, and water quality must be integrated and balanced.

The third witness was the Honorable David Durenberger, United States Senator from Minnesota. Senator Durenberger stated that there is no doubt that ground water contamination is a high national priority. Iowa and Minnesota are "the proverbial tip of the national iceberg. . . . Pesticides are at the heart of the current national debate on ground water protection."

Senator Durenberger suggested that any ground water proposal should use a broad definition of ground water, take a preventive approach to the problem, and use a health-based standard for residue levels.

The last panel was Dr. Stuart Z. Cohen, Manager, Ground Water Programs, Biospherics, Inc, Rockville, Maryland; and Mrs. Diane Cognal of Bakersfield, California. Dr. Cohen gave a brief summary of dibromochloropropane (DBCP), a pesticide detected in the ground water of California. DBCP is a liquid soil fumigant used against nematodes—microscopic worms that destroy root systems of plants—from the mid-1950s to 1979. The chemical is an animal carcinogen, and has been shown to cause sterility in humans and genetic toxicity in laboratory animals. Various epidemiology studies conducted in California suggest but do not prove a positive association between DBCP in drinking water and gastric cancer.

According to a 1984 summary by the State Board of Water Resources in California, approximately 2500 wells contained DBCP and probably half exceeded the action level. In 1977, California and EPA began restricting use of the chemical, but it was not until many years later that all uses were banned.

Dr. Cohen noted that although concentrations of the chemical are variable and often low, the potential number of people that can

be exposed is high. He estimated that the number of wells containing detectable levels of pesticides is probably 100,000 or more and the number of persons exposed could be several million.

Dr. Cohen said that the greatest unknown to the health effects of these compounds was whether a national problem existed, which would be dependent on what health guidance levels will be established for several of these chemicals. Another unknown is predicting concentration levels. Finally he noted that compounding factors made it difficult to establish cause-effect relationships.

Mrs. Cognal testified about ground water contamination in the San Jaoquin Valley in California. She has two children who were enrolled in the North School district in Kern County. In 1979 the school was notified that they had high nitrates and DBCP in their well. For nearly 5 years the children continued to drink contaminated water. Over 12 letters were sent to the school; one was acknowledged. The principal did not know what DBCP was, according to Mrs. Cognal. The school tested the well but their results were negative. The lab used was not State certified to do DBCP testing.

In 1980, the Cognal's son was diagnosed as having suppressed hormones. They were later told that the reason could be the pesticide-contaminated water, which has been linked to sterility in workers. She said her son is growing now.

She noted that there are homes in the Valley where one cannot get water without nitrates and DBCP. Current treatment for DBCP is charcoal filters. However, when the filter is used up, it must be disposed of as solid toxic waste. It is wrapped in plastic and sent to the dump—which is above the ground water table.

MAY 20, 1987, HEARING

On Wednesday, May 20, 1987 the Committee on Agriculture, Nutrition, and Forestry met to hear testimony on the National Academy of Sciences (NAS) report titled *Pesticides in Food: The Delaney Paradox.*

The Honorable Ray Thornton, Chairman of the National Academy of Sciences Committee on Scientific and Regulatory Issues Underlying Pesticide Use Patterns and Agricultural Innovation, was the first witness. Joining Chairman Thornton were three members of the NAS committee: Mr. Donald Bissing, FMC Corporation; Dr. Arthur Upton, New York University; and Mr. Richard Merrill, Dean of the University of Virginia Law School.

Chairman Thornton stated that the committee, at the request of the Environmental Protection Agency, examined the scientific basis for regulation of residues of oncogenic (tumor inducing) pesticides in foods. He emphasized that the report does not address actual exposure to pesticide residues or the safety of individual foods, nor does it suggest any need to change eating habits.

The committee found that the current law, which evaluates residues on raw foods by a less stringent standard than processed foods, is difficult to implement and does not provide the best protection of public health. In contrast, the committee found that a uniform negligible risk standard applied across-the-board to pesticides would virtually eliminate potential dietary oncogenic risks from pesticides, without causing undue hardships for agriculture.

By applying a uniform, negligible-risk standard, the EPA would be replacing "the current crazy quilt of regulations with a pattern that is consistent, sensible, and scientific."

The next witness was Dr. John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, U.S. Environmental Protection Agency. Dr. Moore explained how EPA sets tolerance under the interrelated authorities of FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA). Using a series of charts, he then went on to draw a distinction between actual pesticide residues and the theoretical residue data used for setting tolerances and in preparing the NAS report.

Dr. Moore stated that "for the majority of existing pesticides, EPA does not currently have the kind of detailed data on what happens to residues between the 'farm gate' and the consumer that (are available), for instance, on chlorothalinil for tomatoes. My point in these examples is that the use of * * * assumptions to estimate dietary exposure and risk almost always overstates substantially the potential risk to consumers from pesticide residues in the food supply. * * * (Such an) approach cannot give us defintive answers concerning the actual risks associated with agricultural uses of specific pesticides."

Dr. Moore noted that the EPA's newly computerized Tolerance Assessment System (TAS) for the analysis of dietary risk will enable the agency to use actual risk data in lieu of theoretical data and will allow the Agency to predict the impact of hypothetical decisions. TAS is on-line, but has not yet been implemented pending the resolution of some policy questions.

Dr. Moore concluded by saying that the Academy's thoughtful, balanced recommendations will serve the Agency well.

Members of the final panel were Dr. Dennis R. Heldman, Executive Vice President for Scientific Affairs; and Mr. Edward Dunkelberger, Counsel, National Food Processors Association (NFPA); and Ms. Lawrie Mott, Senior Staff Scientist; and Mr. Al Meyerhoff, Senior Staff Attorney, Natural Resources Defense Council (NRDC).

Dr. Heldman stated that his purpose in testifying was to introduce the Committee to NFPA's work in pesticide residue research. The NFPA's Protective Screen is a program to prevent illegal contamination of raw agricultural products with pesticide chemicals. Since 1965 NFPA has had in place a committee of analytical chemists who conduct a number of tests each year to establish the reliability and to document the expected variability of the analytical procedures used to detect and measure pesticide residues and environmental contaminants.

Dr. Heldman then went on to elaborate on the behavior of pesticide residues in food preparatives systems. He emphasized that while a permissible residue on the raw agricultural product theoretically might result in an illegal processed product through inadvertent concentration during food processing operations, "the NFPA knows of no instance under actual commercial or field test conditions in which the actual need for a 409 tolerance (section 409 of the Food, Drug and Cosmetic Act) has been triggered by concentration phenomenon."

Dr. Heldman stated that analytical work to detect and measure pesticide residues is "notoriously expensive." He said that it makes

little economic sense for industry or government agencies to expend large sums of money and devote limited laboratory resources to the analysis of large number of random samples, but rather that the philosophy behind industry and government monitoring efforts is to selectively sample those situations having the highest probability of occurrence of illegal, unnecessary pesticide residues. He noted that applying this principle would dictate that more resources be devoted to monitoring imports.

Dr. Heldman concluded by saying that the vast majority of permitted residues are removed by normal commercial food preparation operations, and that data demonstrates that the processed food supply is "remarkably free of illegal or unnecessary residues of agricultural control chemicals."

Ms. Mott opened her remarks by saying that the NAS report clearly illustrates the risks posed by pesticide residues in food and underscores the need for immediate and fundamental reform of the FIFRA. She stated that current government programs do not protect consumers from pesticides in food. Points also raised in her testimony were that EPA's tolerances may permit unsafe levels of pesticides in food; tolerances are established without adequate data and are based on outdated dietary consumption data; inert ingredients of toxicological concern are not regulated; tolerances are established for carcinogens; FDA monitoring of food does not accurately identify pesticides in food; and FDA enforcement programs are ineffective.

The NAS report may understate risk from cancer-causing pesticides in food, Ms. Mott asserted. She pointed out that occasionally residues are higher than established tolerances. NAS estimated the cancer risk posed by only 28 food use pesticides and did not examine risks posed by inert ingredients or degradation products. Possible synergism that can occur from simultaneous exposure to pesticides was not considered. The report used mean estimates of food consumption which do not take into account sensitivity of certain subgroups of the population such as children.

Ms. Mott concluded by saying that reforms are necessary to protect the public from cancer-causing pesticides in food. NRDC recommends that EPA immediately implement the Delaney clause as it applies to pesticides in processed foods, and revoke all section 409 tolerances for pesticides that concentrate in processed food. Reforms that would reduce risk include requiring full health and safety testing for pesticides, expediting EPA's procedures for taking dangerous chemicals off the market, requiring regulation of hazardous inert ingredients, and requiring the substitution of noncarcinogenic pesticides for carcinogenic pesticides used in food.

JULY 30, 1987, HEARING

On Thursday, July 30, 1987, the Committee on Agriculture, Nutrition, and Forestry met to hear testimony on legislation to amend the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Chairman Leahy opened the hearing by stating that reform of FIFRA is long overdue. The Chairman said that S. 1516, a bill introduced by him and Senator Lugar, would address many of the inadequacies of current law. Chairman Leahy stated his intention to

move expeditiously on the bill, and thanked Senator Lugar for his cooperation and leadership on FIFRA reform.

Senator Lugar, in a prepared statement, stressed the importance of moving as expeditiously as possible to consider S. 1516. Senator Lugar stated that the most significant aspect of the FIFRA reauthorization was the reregistration of older pesticides, using modern, more comprehensive data to determine safety. He also stressed the importance of adequately funding the Agency so that such an undertaking would have some guarantee of success. He also stated that the bill represented over two years negotiations and compromises among competing interests in the pesticide area.

The Honorable Nancy Landon Kassebaum, United States Senator from Kansas, opened the morning's testimony. Senator Kassebaum testified on her bill, S. 746, which would eliminate the data compensation provisions of FIFRA and provide for the use of an abbreviated application for the registration of generic pesticides. She expressed her support for the patent extension provision, and strongly urged the Committee to link that provision to reform of data compensation. She stated that competition would be useful for the industry, while at the same time substantially lower the cost of pesticides to farmers and expand their purchasing options.

Next to testify was Congressman Mike Synar, Chairman of the Subcommittee on Environment, Energy, and Natural Resources of the Committee on Government Operations, U.S. House of Representatives. Congressman Synar urged the Committee to repeal the indemnification section of FIFRA, section 15. He further urged the Committee to restructure EPA's disposal responsibilities to give the Agency clear authority to monitor the storage and disposal of banned pesticides and to require the manufacturers to bear the cost of these activities. Congressman Synar reaffirmed his support for the inclusion of provisions relating to ground water protection, citizen right-to-know, and public participation.

Senator Leahy then introduced Dr. John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, Environmental Protection Agency. Dr. Moore testified that the Agency has little enforceable authority over storage or disposal of pesticides once the suspension and cancellation orders have been issued, and that the pesticide industry is best equipped to deal with the associated technical issues pertaining to their products.

Dr. Moore proceeded to make the following points in his statement:

(1) Indemnification should be repealed and storage and disposal cost should not be borne by the Federal government.

(2) Reregistration fees should be raised to fully fund the accelerated reregistration program.

(3) The Agency has already begun implementing an inerts strategy and therefore believes that additional legislation in this area is unnecessary. Further, EPA does not support the deadlines that the bill would impose.

(4) The Agency should have discretion through rulemaking to adjust its certification and training requirements.

(5) EPA is working on farm worker safety regulations and no additional legislation is necessary.

(6) S. 1419 represents substantial progress over legislative proposals developed last year and retained in H.R. 2463. However, the Agency has concerns about the establishment of ground water residue guidance levels and the definition of ground water, and cannot support the bill at this time.

Senator Fowler assumed the chair and introduced a panel consisting of Ms. Janet Hathaway of the Natural Resources Defense Council, Ms. Maureen Hinkle of the National Audubon Society, and Ms. Margaret Seminario of the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO).

Ms. Janet Hathaway testified that S. 1516 was a substantial step toward an effective federal pesticide law. NRDC would like to strenghten the bill by adding provisions for ground water protection, citizen suits, export controls, worker protection and right-to-know, EPA recalls of imminently hazardous pesticides, and improved disposal requirements. NRDC opposes liability exemptions and preemption of state authority to set tolerances. NRDC opposes a proposal to require identical and concurrent data by Federal and State agencies. The indemnification and fees sections are important improvements over last year's legislation, though repeal of indemnification would be preferable. Although S. 1419 would greatly enhance protection of ground water, NRDC does not support a negligible risk standard for carcinogenic pesticides.

Ms. Maureen Hinkle testified that S. 1516 is an improvement over last year's bill. She related that Audubon is opposed to preemption of State's tolerances and farmer liability exemptions; Audubon urges the Committee to incorporate S. 1419 into S. 1516; and Audubon requests retention of existing law that places the burden of proof on the registrant and assurance that section 505 of the bill does not implicitly shift the ultimate burden of proof. Ms. Hinkle suggested that the Committee adopt a citizen suit provision similar to the one contained in the Toxic Substances Control Act, urged an amendment to require registrants to submit an acceptable disposal plan at reregistration, and urged that patent terms for DNA products not be extended without companion legislation in the authorizing committee.

Ms. Margaret Seminario testified that S. 1516 is a major step toward reforming FIFRA. The AFL–CIO urges stronger provisions on worker protection, citizen enforcement, and ground water. For worker protetion, the bill should set forth protective measures to be included in health and safety standards and should prohibit employer discrimination against workers who exercise their rights under this law, and should require basic records to be maintained on pesticide use and hazards.

Mr. Ralph Nader was the last witness of the morning session. Mr. Nader testified that while S. 1516 represents an improvement over the present FIFRA statute because it would not preempt State standards or exempt farmers from liability, it lacks critical provisions. Nader recommended immediate suspension of aldicarb, alachlor, daminozide, captan, and chlordane; repeal of indemnification; banning the export of cancelled and suspended pesicides; adding a citizen suit provision similar to the one in the Clean Water Act; and adding right-to-know and 30-year recordkeeping requirements and requirements for health and efficacy studies. Mr.

Madar stated that patent term extension should not be graned if the bill includes preemption or liability and does not include citizen suits and mechanisms that require removal of inadequately tested pesticides from the market if deadlines are not met.

The afternoon session, chaired by Senator Harkin, opened with a panel of witnesses representing the agricultural chemicals industry. Panelists included Mr. John Hagaman and Dr. Jack Early of the National Agricultural Chemicals Association (NACA), Mr. Warren Stickle of the Chemical Producers and Distributors Association, Mr. Dennis Burchette of ConAgra Inc., and Mr. Ralph Engel of the Chemical Specialities Manufacturers Association.

Mr. John Hagaman urged the Committee to support the data compensation and patent term restoration provisions in S. 1516. Dr. Jack Early testified that S. 1516 is a weaker bill than passed the Senate last year because it deletes provisions on ground water protection, tolerance uniformity, and farmer liability, modifies indemnification, and imposes excessive reregistration fees. NACA opposes prohibiting exports of banned pesticides. NACA opposes S. 1419 because of the definition of ground water, the goals for water quality standards, and requirement for state programs. NACA prefers the ground water proposal in H.R. 2463 to any past or current proposals on ground water before the Senate.

Mr. Dennis Burchette testified on behalf of ConAgra. ConAgra would support the patent term provisions of S. 1516 if amended to allow testing of a patented pesticide and submission of a registration application prior to the expiration of the patent. ConAgra proposes that the data compensation section be amended to provide that compensation include a fair share of the cost of the data, as well as consideration of the value of the data. Value compensation would be limited to a maximum amount of 25 percent of the estimated net profits over the first three years of sales. Compensation would be payable over a maximum period of three years.

Dr. Warren Stickle testified on behalf of the Chemical Producers and Distributors Association (CPDA). CPDA supports S. 746. CPDA recommends an amendment to clarify that data compensation should be an equitable sharing of the costs of data and an amendment to allow testing and iling of an application for a registration before the expiration of a patent. CPDA is opposed to the reregistration fees proposal contained in S. 1516. CPDA would support patent term restoration only if generic registration and testing prior to patent expiration is allowed. CPDA supports a fast track registration for "me-too" products and label changes.

Mr. Ralph Engel testified on behalf of the Chemical Specialties Manufacturers Association (CSMA). CSMA is opposed to reregistration fees and indemnification changes. Mr. Engle recommended that a new section be added to mandate that States take into consideration the differences between agricultural and non-agricultural pesticides. CSMA supports a fast track registration for "me too" products and label changes. CSMA supports an amendment to establish identical and concurrent testing requirements among Federal and State agencies.

The second panel consisted of witnesses representing environmental and public interest organizations. Panelist included Mr. Rick Hind of U.S. Public Interest Research Group; Mr. David

Baker of Friends of the Earth; Ms. Michelle Meier of Consumers Union; Ms. Franci Livingston of Public Citizen's Congress Watch; and Mr. Jay Feldman of the National Coalition Against the Misuse of Pesticides.

Mr. Rick Hind testified on behalf of U.S. Public Interest Research Group (PIRG). PIRG applauded the exclusion of preemption and liability exemption from S. 1516. Mr. Hind recommended repeal of indemnification and disposal requirements; prohibition of exports of suspended, cancelled and restricted pesticides; and adoption of a ground water provision at least as protective as S. 1419, but preferably stronger. He further recommended fees to cover the entire cost of reregistration; a citizen suit provision similar to section 505 of the Clean Water Act; a comprehensive right-to-know provision; a thirty-year record keeping requirement in the worker safety provision; and whistle blower protection for farm workers and applicators.

Mr. David Baker testified on behalf of Friends of the Earth (FOE). FOE suggested a three-stage approach to pesticide management: Repeal FIFRA; allow the use of a toxic pesticide only when it is proven essential, safe and effective; and encourage development of non-chemical alternatives for pest management. All FIFRA bills to date are inadequate to protect public health. He stated that S. 1516 is inadequate, though an improvement over current law, and urged members to strengthen the bill.

Ms. Michelle Meier and Ms. Franci Livingston testified on behalf of Consumer Union and Public Citizen's Congress Watch, respectively. They expressed their support for exclusion of preemption, and a liability exemption. The fee schedule is an improvement, but reregistration should be fully funded by fees, Ms. Meier stated. Consumers Union and Public Citizen urged an amendment to cancel all pesticides that have not been reregistered by a fixed deadline; repeal of indemnification and disposal requirements; and addition of recall authority and a citizen suit. Consumers Union and Public Citizen oppose establishing identical and concurrent data requirements among Federal and State agencies.

Mr. Jay Feldman testified on behalf of the National Coalition Against the Misuse of Pesticides (NCAMP). He stated that S. 1516 is a weak bill. While S. 1516 corrects the disincentive for the Agency to suspend a product, it leaves open the possibility that taxpayers may have to pay for indemnification. NCAMP opposes the neglible risk standard in S. 1419. NCAMP advocates revising FIFRA to conform with other environmental statutes: restrict the use of pesticides to cases where they are necessary to avoid greater risk, use health-based standards, consider alternatives, and allow citizen suits among other things.

The next witness was Mr. James Aidala of the Congressional Research Service who testified on the regulatory history of certain termiticides and on S. 1427, a bill to cancel the registration of chlordane and other cyclodienes. In 1978, EPA canceled most uses of chlordane, except for termite control. It has been reported that new air monitoring studies indicate an increased lifetime probability of contracting cancer of three in one thousand as a result of currently approved uses of chlordane. Mr. Aidala testified that S. 1427 may be warranted, though unprecedented, if Congress determines

that there is a sufficiently high risk to public health and the environment.

The final panel consisted of witnesses representing agricultural and food interest organizations. These panelists included Mr. Mark Maslyn of the American Farm Bureau Federation; Ms. Claudia Fuquay of the United Fresh Fruit and Vegetable Association; Mr. Lawrence Graham of the National Food Processors Association; Mr. William Darrow of the Grocery Manufacturers of America; and Mr. John Hall of the American Wood Preservers Institute.

Mr. Mark Maslyn, the American Farm Bureau Federation (AFBF), testified that AFBF supports reregistration, but opposes increased fees. AFBF believes that S. 1419 could be more flexible and accommodate the needs of agriculture while still maintaining its preventive approach. AFBF supports a liability exemption for farmers who use pesticides in compliance with label instructions, and encouraged the Committee to include uniform tolerance provisions in the bill.

Ms. Claudia Fuquay, United Fresh Fruit and Vegetable Association, testified that United supports accelerated reregistration and the closing of data gaps. She urged requiring EPA to give high priority to registrations of new pesticides for use on fruits and vegetables. United supports a minor use fee waiver, the IR-4 provision, and uniform tolerances. She suggested that worker health and safety be deleted from S. 1516. United would like an amendment to prohibit states from denying a registration because another product is available. United opposes language in S. 1419 that treats current drinking water and potential drinking water in the same manner.

Mr. Lawrence Graham, the National Food Processors Association, testified that NEPA supports accelerated reregistration, inclusion of a discretionary fee waiver provision, uniform tolerances, a liability exemption, and the ground water language of H.R. 2463.

Mr. William Darrow, on behalf of the Grocery Manufacturers of America, testified in favor of a system of uniform tolerances.

Mr. John Hall, the American Wood Preservers Institute (AWPI), testified in support of S. 1516, as long as it is not seen as a starting point for negotiation on possible amendments. AWPI does not support S. 1419, but supports the ground water language in H.R. 2463.

FEBRUARY 17, 1988, MARKUP

On Wednesday, February 17, 1988, the Committee on Agriculture, Nutrition, and Forestry met to markup S. 1516.

The Chairman moved, on behalf of Senator Lugar and himself, that the Committee adopt S. 1516 as the markup vehicle and that the Committee adopt those sections of S. 1516 that had identical sections in S. 2035. S. 2035, a comprehensive FIFRA reform bill, was introduced on February 4, 1988, by Senators Heflin, Helms Cochran, and Pryor and referred to the Agriculture Committee.

The Chairman explained that these identical sections, which included provisions for special review, applicator training and certification, hearing procedures, penalties, and revocation of tolerances for suspended and canceled products, were not controversial. The Chairman clarified that sections 203, 204, and 207 regarding data

compensation, section 301(j) regarding fees, section 2301 on appropriations, and section 2402 on patent term restoration were not included in the motion. Without objection, the Committee agreed top the motion.

The Committee then turned to the consideration of the fee schedules in S. 1516 and S. 2035. The Chairman noted the fee schedule in S. 1516 would raise $113 million and the schedule in S. 2035 would raise $44 million of the $260 million needed to fund reregistration. After some discussion, the Chairman suggested that staff be instructed to work on a fee schedule that would raise $100–110 million and present the Committee with a proposal at the next meeting.

Senator Bond offered an amendment to section 15 of the Act that would allow farmers and other end users of pesticides to be indemnified for stocks of suspended and canceled pesticides through the Judgment Fund of the Treasury, but would require a line-item advance appropriation for indemnification of any other party. (S. 1516 as introduced would have required that all indemnification be subject to a line-item advance appropriation. S. 2035 would have retained current law.) Senator Heflin objected to adopting the amendment and asked for additional time to consider it.

The Chairman then offered, on behalf of himself and Senator Lugar, and amendment on storage and disposal of suspended and canceled pesticides. The amendment would authorize EPA to require a pesticide registrant to develop procedures for storage and disposal of the pesticides and its containers, transfer the responsibility for transportation, storage, and disposal of the products from the EPA to the registrant, provide for Federal oversight of the foregoing activities, and authorize a recall program in situations where a canceled pesticide posed a public health risk. Senator Bond asked Mr. John Moore of the EPA a number of questions regarding storage and disposal and the Committee agreed to resume consideration of the amendments at the next markup.

The Chairman informed the Committee that Senator Lugar, Senator Bond, and he were sending letters to the Congressional Research Service (CRS) and the General Accounting Office (GAO) requesting a legal analysis of the extent to which farmers may be liable for damages or remedial action under current Federal envirnomental statutes for the use of a pesticide.

MARCH 30, 1988

On Wednesday, March 30, 1988, the markup reconvened. The Chairman noted that the unfinished business from the previous markup was fees, indemnification, and storage and disposal. The Chairman also distributed copies of a letter from the Senate Environment and Public Works Committee regarding their intention to seek sequential referral of S. 1516 if it contained an exemption for farmers from liability under Federal environmental statutes or a ground water protection provision, among other things.

Senator Lugar then offered, on behalf of himself and Chairman Leahy, a compromise fee proposal. Senator Lugar stated that his amendment would generate all the funds necessary to complete the reregistration program within nine years and would eradicate the

backlog or registration applications for products that are identical or substantially similar to already registered products. Senator Lugar proposed that the fee schedule in S. 2035 be adopted, which would raise $26–$44 million, and be supplemented by adding an annual maintenance fee for a period of nine years. Maintenance fees would apply to each of the estimated 40,000 registered pesticide products and would range from $425 to $100. The maintenance fee system would raise approximately $14 million annually for a total of approximately $126 million over nine years. The total amount expected to be generated from both fees is appproximately $160 million for a total of $270 million when combined with the appropriated funds. After some discussion, the Committee unanimously approved the Lugar amendment.

Senator Melcher offered an amendment to provide for "fast track" consideration of registration applications for products that are identical or substantially similar to already registered products. The amendment would require the Administrator to notify the applicant within 45 days whether the application is complete and within 90 days after receiving a complete application whether the application has been granted or denied. Without objection the amendment was approved.

The Committee returned to Senator Bond's indemnification amendment. Senator Heflin stated that, while the Committee supported the Bond amendment, he was concerned about the appropriation requirement for dealers and distributors who might be unaware of an imminent suspension. Senator Heflin asked that action on the Bond amendment be delayed until further consideration was given to indemnificaiton of dealers and distributors.

APRIL 20, 1988

The Committee reconvened for the final markup on April 20, 1988.

The Committee returned to the issue of indemnification. Senator Lugar proposed that the Committee adopt the Bond amendment and provide for indemnity payments in special circumstances to dealers and distributors who are non-registrants of the suspended and canceled pesticide. Such non-registrants would be eligible to submit a claim to the Administrator of the EPA who would have the discretion to make a recommendation for payment from the Judgment Fund. Special circumstances would mean cases of bankruptcy, involvency, or other legitimate reasons as to why a registrant would be unable to take back the canceled products or reimburse its dealers and distributors. The amendment further would require that producers provide reimbursement for suspended and canceled products, or provide a written notice that the products are not subject to reimbursement. The amendment was approved by voice vote.

The Committee returned to the other item of unfinished business, storage and disposal. Senator Lugar proposed an amendment that would provide for limited cost sharing among EPA and manufacturers for storage costs incurred for suspended and canceled, pesticides, require EPA to develop disposal criteria within 12 months of enactment of the bill, and require EPA to work with the

manufacturer to develop environmentally sound disposal plans to be carried out by the manufacturers and the EPA in order that the disposal of suspended and canceled products can occur as expeditiously as possible, Senator Lugar noted.

Senator Bond asked whether the Committee should consider requiring the Administrator to determine whether the registrant has the financial resources to carry out a recall. Senator Lugar stated that the point was well taken. The Committee adopted the amendment with the financial capability provision.

Senator Helms then offered the ground water provision of S. 2035 as an amendment to S. 1516 and the Committee began an extended debate. The Chairman questioned whether the Committee wanted to add a ground water provision and run the risk of having the bill referred to another committee so late in the session. Senator Heflin responded that he was concerned that without a ground water provision in the bill, the Committee might appear to be abdicating jurisdiction over the issue. Senator Lugar suggested that the Committee report the ground water language of S. 2035 separately so that jurisdiction could be asserted without the risk of delaying floor consideration of the rest of the reform package.

The ground water amendment was laid aside temporarily while the Committee considered the Bond amendment on farmer liability. Senator Bond stated that his amendment would exempt farmers from liability for damages when pesticides are applied according to labeling instructions, unless the agricultural producer acted negligently. Senator Bond noted that, while there is no precedent of a farmer being held liable under Federal law, State law has raised the question about farmer liability. He further stated that while the analyses from CRS and GAO indicated that there currently are exemptions under Superfund for farmers, and that under current EPA policies and practices, liability does not appear to be a problem, the GAO reported that the potential exists for farmers who have properly applied a pesticide to be required to undertake abatement-type actions and incur the expenses thereof in an emergency situation. The Committee set aside the amendment pending refinement of the language on the farmer's burden of proof.

The Committee returned to the Helms ground water amendment and continued debating the merits of the provision and the potential for jurisdictional claims delaying floor action on the bill until late in the session. The members then voted on the Lugar motion to report the ground water provision separately. The motion was not approved by a vote of 5 to 12. The Helms ground water amendment was then approved by voice vote.

Senator Melcher next offered a two-part amendment. The first part would provide for user participation in label changes made by by rulemaking. The second would require the Administrator, in the implementation of other statutes through FIFRA, to assure that his actions are based on the best sceientific and commercial data available and have been formulated under procedures that offered an opportunity for comment by affected parties. The amendments were approved by voice vote.

The members next approved the patent term restoration and data compensation provisions of S. 1516. Senator Melcher indicated

his interest in offering a data compensation amendment on the floor. The Chairman noted that the patent term provision might be subject to a sequential referral to the Judiciary Committee.

The Committee then considered an amendment by Senator Cochran on wood preserving pesticides. The Cochran amendment would provide that in regulating the in-plant application of wood preserving pesticides under FIFRA, the Administrator must, by label requirement, assure that excess amounts of pesticides that are collected and contained to be reapplied in the wood preserving process must be regulated as a pesticide. Dr. Moore suggested that the language specify that the reapplication must be by the same users, and the Committee adopted the amendment as modified.

Senator Fowler offered, and the Committee accepted, an amendment to improve FDA monitoring of pesticide residues in agricultural imports and to require prior informed consent for the export of pesticides to other countries that the Administrator determines to have an existing and effective pesticide regulatory program.

Next, Senator Melcher offered, on behalf of himself and Senator Boschwitz, an amendment that would require pesticide testing requirements to be coordinated and synchronized among Federal and State agencies. Senator Melcher stated that the amendment was needed because the EPA and some States have different timetables for testing. Senator Melcher stated that the amendment was designed to avoid duplicate testing but not to interfere with a State's right to ask for additional testing.

Senator Wilson offered a second degree amendment to the Melcher amendment that provided that nothing in the Melcher amendment shall be interpreted as adversely affecting the authority of States to test, regulate, or otherwise control the use of pesticides. Senator Wilson stated his preference for not adopting the Melcher amendment, but stated that if it were adopted his qualification was necessary. Senator Wilson stated that California's additional data requirements are such that 85 percent of the applications for California registrations require additional information beyond that required by the EPA. After some debate, the Committee recessed for the morning.

During the afternoon session, the Committee approved amendments offered by the Chairman concerning the apportionment of reregistration fees for registrants who have not been actively marketing their products, a DDT study, and a biotechnology study.

The Committee resumed consideration for the Melcher and Wilson amendments. Senator Wilson noted the opposition of the National Governors Association to requiring identical and concurrent pesticide data collection by the EPA and States. The Committee entered into an extended debate over whether the Melcher amendment would preempt a State's authority to test or regulate pesticides. The Wilson amendment was then adopted by a roll call vote of 14 to 4. The Melcher amendment was adopted by voice vote.

The Committee then returned to the issue of farmer liability. Senator Bond explained the modification in the language to clarify what constituted a farmer's burden of proof. The amendment would require the farmer to certify to the Administrator that the application was in compliance with the labeling and applicable law. The contents of a certification would contain the approximate date

of application, name of the pesticide, rate of application, and the location of application. Senators Breaux and Conrad raised concerns about the distinctions between the term "release" and "application" in the language. The Chairman agreed that further clarification should be made if necessary. The Committee agreed to the amendment by voice vote.

Senator Harkin offered and the Committee adopted an amendment that would require inert ingredients that are active ingredients in other pesticide formulations to be listed as such on the pesticide label.

The Committee approved an authorization for appropriations and agreed to order reported the amended bill.

ROLLCALL VOTES

In accordance with paragraph 7(b) and 7(c) of Rule XXVI of the Standing Rules of the Senate, it is announced that—

(1) A motion was offered by Chairman Leahy to consider the Heflin-Helms ground water amendment as a separate piece of legislation. The motion was not approved by a vote of 5 to 12 as follows:

YEAS	NAYS
Harkin*	Melcher
Conrad	Pryor
Daschle	Boren
Lugar	Heflin
Leahy	Fowler
	Breaux
	Helms
	Cochran
	McConnell
	Bond
	Wilson
	Karnes

*By proxy.

(2) A second-degree amendment was offered by Senator Wilson to the Melcher amendment on data coordination. The Wilson amendment states that the Melcher amendment" shall not be interpreted as adversely affecting the authority of States to test, regulate, or otherwise control the use of pesticides". The amendment was approved by a vote of 14–4 as follows:

YEAS		NAYS
Harkin	Helms	Melcher
Conrad	Cochran	Boren*
Fowler	McConnell	Boschwitz
Daschle	Bond	Heflin
Breaux	Wilson	
Lugar	Karnes*	
Dole*	Leahy	

*By proxy.

SECTION-BY-SECTION ANALYSIS

Section 1—Short title

Section 1 provides that the bill may be cited as the "Federal Insecticide, Fungicide, and Rodenticide Reform Act of 1988" and supplies a table of contents.

Section 2—References

Section 2 states that, except as otherwise provided in the bill, an amendment, or repeal of a section or other provision will be considered to be made to a section or provision of the Federal Insecticide, Fungicide, and Rodenticide Act ("the Act").

TITLE I—DEFINITIONS

The sections under title I amend definitions under section 2 of the Act.

Section 101—Applicator

Section 101 revises section 2(e) of the Act, which contains definitions relating to persons who apply pesticides. As revised, section 2(e) provides that—

(1) the term "commercial applicator" means a person (whether or not the person is a private applicator with respect to some use) who (a) uses or supervises the use, for any purpose or on any property, of any pesticide that is classified for restricted use; (b) uses or supervises the use of any pesticide (other than a pesticide that the Administrator determines may be applied without the need for training) for hire as the principal part of the person's business or work; or (c) uses or supervises the use of any pesticide as an employee of a person that uses or supervises the use of any pesticide for hire as the principal part of the person's business or work. The term does not include a person who uses or supervises the use of a pesticide as a private applicator. It is the intent of the Committee that, in defining the term "principal part" in implementing this definition, the Administrator exclude from the commercial applicator category persons engaging in the occasional use of pesticides, but include those persons who use pesticides with such regularity and frequency as to pose a potential threat to the public health, the environment, or themselves without the training required of commercial applicators;

(2) the term "private applicator" means a person who uses or supervises the use of any pesticide that is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by the person or the person's employer, or on other property if applied without compensation (other than trading of personal services between producers of agricultural commodities).

(3) the term "certified applicator" means a commercial or private applicator who is certified under section 4 or 11(b) of

the Act (which is substantially amended under section 401 of the bill); and

(4) with respect to the term "under the direct supervision of a certified applicator", unless otherwise prescribed by its labeling, a pesticide is considered to be applied under the direct supervision of a certified applicator if it is applied by a person acting under the direct supervision and the instructions and control of a certified applicator who is available if and when needed, even though the certified applicator is not physically present at the time and place the pesticide is used.

The new definitions of "private applicator" and "under the direct supervision of a certified applicator" are substantially the same as existing law. The new definition of "certified applicator" revises the current definition in the first sentence of section 2(e)(1) to reflect the other changes in the Act made by title IV of the bill. The second sentence of section 2(e)(1) is deleted, but substantially retained in the definition of "to distribue or sell" in new subsection (rr) of section 2, to be added by section 106 of the bill. The new definition of "commercial applicator" expands the definition in current law by adding the provision described in clauses (b) and (c) of item (1) above.

Section 102—Ingredient Statement

Section 102 amends section 2(n) of the Act to redefine the term "ingredient statement" to mean a statement that contains (1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients in the pesticide; (2) the name of each inert ingredient in a pesticide that the Administrator determines must appear in the ingredient statement because of the hazard that the Administrator has determined may be posed by the toxicity, use pattern, and concentration level of the inert ingredient in the pesticide; (3) the name of each ingredient in the pesticide that is present in any other registered pesticide as an active ingredient and, if the Administrator determines that such pesticide ingredient is an inert ingredient in the pesticide, a note stating that the pesticide ingredient is an active ingredient in other pesticide formulations; (4) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluable arsenic, calculated as elementary arsenic; (5) any other information concerning the chemical composition or identity of any active ingredient of the pesticide, including information on chemical equivalency, that the Administrator requires to appear in the ingredient statement so that the nature of the active ingredient is accurately represented; and (6) the name of any inert ingredient for which the Administrator has required additional data under new subsection (g)(5) of section 3 because the inert ingredient is listed under new subsection (g)(1) as appearing to cause a pesticide to meet or exceed a criterion for initiating a public interim administrative review ("special review") under the Act.

The definition under current law consists only of the items described in clauses (1), (3), and (4) of the preceding sentence.

Section 103—Misbranded

Section 103 amends section 2(q)(1) of the Act, which defines the term "misbranded," by listing a number of situations in which pesticide would be considered misbranded. A new provision to the list in section 2(q) is added to provide that a pesticide intended for export and substantially similar in composition and use pattern to a registered pesticide is misbranded if the label is not written in an appropriate language, as required by new subsection (a)(3)(A) of section 17 of the Act (to be added by section 1501 of the bill), or does not contain the same health, safety, and hazard precautions as the pesticide registered under the Act for uses similar to those to which the exported pesticide may be put.

Section 104—Pesticide

Section 104 amends section 2(u) of the Act to include in the definition of the term "pesticide" any substance or mixture of substances intended for any of the antimicrobial purposes described in clauses (1) through (5) of the definition of "antimicrobial" in section 106.

Section 105—To use any registered pesticide in a manner inconsistent with its labeling

Section 105 amends section 2(ee) of the Act to provide that the term defined therein—"to use any registered pesticide in a manner inconsistent with its labeling"—does not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling (unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency); or (2) employing any method of application not prohibited by the labeling (unless the labeling specifically state that the product may be applied only by the methods specified on the labeling). The words in parentheses are those that are added to current law by the amendment.

Section 106—Additional definitions

Section 106 amends section 2 by adding new subsection (ff) through (rr). New subsection (ff) defines the term "antimicrobial." Under the new definition, the term means any active ingredient that is contained only in pesticides that are not registered for any food or feed use and that are—

(1) sanitizers intended to reduce the number of living bacteria or viable virus particles on inanimate surfaces or in water or air;

(2) bacteriostats intended to inhibit the growth of bacteria in the presence of moisture;

(3) disinfectants intended to destroy or irreversibly inactivate bacteria, fungi, or viruses on surfaces or in water or air;

(4) sterilizers intended to destroy viruses and all living bacteria, fungi, and their spores on inanimate surfaces; or

(5) fungicides or fungistats.

New subsection (gg) defines the term "container" to mean any package, can, bottle, bag, barrel, drum, tank, or other containing-

device (excluding spray applicator tanks) used to enclose a pesticide or pesticide-related waste.

New subsection (hh) defines the term "country of import" to mean any foreign country, including the country of ultimate destination and all transit countries, to which a pesticide, device, or active ingredient is exported from the United States.

New subsection (ii) defines the term "drinking water well" to mean a well or spring currently supplying water for human consumption.

New subsection (jj) defines the term "exporter" to mean any person who arranges to transport, or who transports, any pesticide, device, or active ingredient to any country of import.

New subsection (kk) defines the term "ground water" to mean water below the land surface in a zone of saturation.

New subsection (ll) defines the term "ground water residue guidance level" to mean a ground water residue guidance level established under section 1429 of the Public Health Service Act (42 U.S.C 300h-8).

New subsection (mm) defines "ground water sampling point" to mean a public or community water supply, a private water supply, a spring, or a monitoring well or other ground water source, if the well or source is reasonably designed and of adequate depth to permit the collection of representative ground water samples.

New subsection (nn) defines the term "outstanding data requirement." Under the new definition, the term means a requirement for any study, information, or data necessary to make a reregistration determination under the Act that has not been submitted to the Administrator, or if submitted, that the Administrator determines must be resubmitted because it is not valid, complete, or adequate to make a reregistration determination. In determining whether a study is valid, complete, or adequate, the Administrator must examine, at a minimum, relevant protocols, documentation of the conduct and analysis of the study, and the results of the study to determine whether the study and the results of the study fulfill the data requirement for which the study was submitted to the Administrator.

New subsection (oo) defines the term "pesticide testing facility" to mean any person that conducts any test, study, survey, or investigation of the properties, effects, or behavior of any pesticide (or any ingredient, metabolite, or degradation product thereof) on its own behalf or on behalf of any registrant, applicant for registration, or other person who sells or distributes the pesticide (or contemplates selling or distributing it). The term does not include any person solely on account of the person's participation as a cooperator in field testing of a pesticide in compliance with an experimental use permit issued under the Act.

New subsection (pp) defines the term "potential sources of drinking water". Under the new definition, the term means an aquifer or portion of an aquifer system that may supply a drinking water well. Any determination as to whether an aquifer or a portion of it is a potential source of drinking water must include (1) whether there is water in sufficient quantity of quality to supply a drinking water well; (2) hydrogeological considerations and depth to drinking water; and (3) geographic considerations including any State

criteria or guidelines established under section 1428 of the Public Health Service Act (42 U.S.C. 300h–7) or other State authority.

New subsection (qq) defines the term "reliable analytical data" to mean scientific information that verifies the presence of a pesticide in a ground water sample and that is of a reliable scientific quality according to generally recognized standards and good laboratory pesticides for sampling and analysis of pesticides in ground water.

New subsection (rr) defines the term "to distribute or sell". Under the new definition, the term means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver. The term does not include the holding or application of registered pesticide products or use dilutions thereof by any applicator who provides a service of controlling pests without delivering any unapplied pesticide to any person so served.

TITLE II—REGISTRATION OF PESTICIDES

Section 201—Requirement of registration

Section 201 makes a conforming amendment to section 3(a) of the Act to reflect new subsection (rr) of section 2, which defines the term "to distribute or sell."

Section 202—Limitation on unregistered pesticides

Section 202 adds a new provision to subsection (a) of section 3 of the Act. Subsection (a), as revised by section 201 of the bill, prohibits the distribution or sale of an unregistered pesticide. The added provision states that, to the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under the Act that is not the subject of an experimental use permit or an emergency exemption.

Section 203—Data compensation

Section 203 amends section 3(c)(1)(D)(ii) of the Act to clarify that data submitted in support of the safety of an inert ingredient are subject to the data compensation provisions of the Act (as limited by the exclusive use provisions of such section) for the 15-year period following the date the data were originally submitted.

Section 204—Data compensation and arbitration

Section 204 amends section 3(c)(1)(D) relating to the compensation of original data submitters.

Under current law, clause (ii) of section 3(c)(1)(D) provides that the Administrator may consider data submitted under the Act, without the permission of the original data submitter, to support an application by any other person (the "applicant") within the 15-year period after the data were first submitted if the applicant makes an offer to compensate the original data submitter. The data must have been first submitted after December 31, 1969, and are subject to the exclusive use provisions of clause (i). The terms and amount of compensation are to be fixed by agreement between the

original data submitter and the applicant or, failing agreement, binding arbitration as provided for in clause (ii). Either party may initiate the binding arbitration proceedings if they cannot reach agreement on the terms and amount of compensation within 90 days after the applicant's offer to compensate is delivered to the data submitter. The parties to the arbitration must share equally in the fees and expenses of the arbitrator.

Section 204 redesignates clause (iii) as clause (iv) and provides for a new clause (iii). New clause (iii) provides that, in the case of a pesticide for which the patent has expired, the terms and amount of compensation for data that were submitted for that pesticide, to be paid by a person who intends to file an application for registration of a pesticide that cites such data, may be fixed *before* the submission of the application by arbitration under clause (ii) initiated by the applicant. The arbitration would be binding on the original data submitter and also would be binding on the applicant after the date the application is submitted. No official or court of the United States would have power or jurisdiction to review any such finding or determination of the arbitrator, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint, with supporting affidavits, attesting to specific instances of such fraud, misrepresentation, or other misconduct.

Each party to the first arbitration under clause (iii) to determine the terms and amount of compensation for the use of particular data would share equally in the payment of the fees and expenses of the arbitrators and would each pay its own attorney's fees. In all subsequent arbitrations under clause (iii) to determine the terms and amount of compensation for the use of the data, the party to the subsequent arbitration who seeks to cite the data of the original data submitter must pay the fees and expenses of the arbitrators and the attorney's fees of the original data submitter.

Clause (iii) also provides that clause (ii) applies to arbitrations under clause (iii), except as otherwise provided in clause (iii).

Section 205—Data in support of registration

Section 205 amends section 3(c)(2)(A) of the Act to provide that if the Administrator requires additional information on an inert ingredient to support the registration of a pesticide, a sufficient time must be permitted for registrants to obtain the information.

Section 206—Additional data to support existing registrations

Section 206 amends clauses (i) and (ii) of section 3(c)(2)(B) of the Act relating to the joint development of additional data to support an existing registration of a pesticide by two or more registrants.

Clause (i) currently provides that if the Administrator determines that additional data are required to maintain in effect and existing registration of a pesticide, the Administrator must notify the registrant of each pesticide to which the determination relates and provide a list of the registrants to any person. Clause (i) is amended to apply also to existing registrations of groups of pesticides.

Under current law, each registrant of a pesticide for which additional data are needed to support the registration must provide evi-

dence, within 90 days after receipt of notification by the Administrator, that the additional data are needed, and that it is taking appropriate steps to secure the data. Subclause (I) of new clause (ii) of the bill expands this provision to include taking appropriate steps to submit the data.

Clause (ii) currently provides that two or more registrants may agree to develop jointly, or share in the cost of developing, such data if they agree to advise the Administrator within 90 days after notification; and that a registrant who agrees to share in the cost of data is entitled to examine and rely on the data in support of the registration. This provision is amended and included as new subclause (II) of clause (ii).

New subclause (II) provides that two or more registrants may agree to develop jointly, or to share in the cost of developing data. Any registrant who enters into such an agreement, or who offers to agree to share in the cost of development of such data, is entitled to examine the data and rely on the data to maintain or obtain registrations under the Act or under State law. An offer to enter into such an agreement may be accepted at any time and may not be withdrawn without the consent of the person to whom the offer was made.

Section 206 also amends the provision of clause (iii) of section 3(c)(2)(B) concerning binding arbitration proceedings to establish the terms of the data development arrangement or agreement. As amended, clause (iii) provides that, if at the end of 60 days after two or more registrants have entered into an agreement under clause (ii), the registrants have not further agreed on the terms for reaching such an agreement, any of the registrants may initiate binding arbitration proceedings to fix such terms by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by the Service.

Section 206 adds a new clause (vi) to section 3(c)(2)(B) of the Act. New clause (vi) requires that whenever tests of a type specified in the guidelines promulgated under subparagraph (A) or (B) of section 3(c)(2) are requested by more than one Federal or State agency to support a pesticide registration, such test with respect to such aspects as test protocols, timetables, and standards of review, must be coordinated and synchronized among the agencies so as to avoid unnecessary repetition and redundancy. Within 1 year after the date of enactment of this clause, the Administrator must, by rule, develop and implement procedures for such coordination and synchronization so as to result in identical test methodologies acceptable to all the agencies. In the case of unresolved dispute, the agencies must submit the facts to the Scientific Advisory Panel established under section 25(d) of the Act for a recommendation that would be considered by the agencies for a final determination relative to coordination and synchronization. New clause (vi) further provides that nothing in the clause shall be interpreted as adversely affecting the authority of States to test, regulate, or otherwise control the use of a pesticide.

The goal of clause (vi) is to create a procedure to avoid unnecessary duplicative or redundant tests, while preserving all existing regulatory powers of the States and the Environmental Protection Agency. State and EPA authority with regard to testing, regulating

or controlling pesticides is not preempted by this clause. The authority to test includes ordering registrants or other parties to perform tests, evaluating data submissions, and establishing timetables for submission of data, as well as standards of review for such data.

Clause (vi) requires EPA to establish a procedure for coordinating test methodologies or protocols to minimize the number of tests required to satisfy identical State and Federal requirements. States will retain their power to set higher standards for test data and to require data more quickly than the Federal government; the Administrator will also retain such authority. Futher, there should be no delay with regard to current State or Federal reregistration timeframes while EPA develop coordination and synchronization procedures, nor after procedures are developed. The recommendation from the Scientific Advisory Panel is designed to provide guidance to the disputing agencies but is not binding on either Federal or States agencies.

Section 207—Compensation for data on inert ingredients

Section 207 amends the provisions of section 3(c)(2)(D) of the Act (which contains the so-called "formulator exemption") to add a new requirement that no applicant for registration or amended registration of a pesticide, who proposes to purchase an inert ingredient from another person, to formuate the pesticide, may be required to offer to pay reasonable compensation otherwise required by the Act for a study concerning the inert ingredient if any portion of the cost of the study will be or could be included in the price of the purchased ingredient.

Section 208—Expedited registration of similar applications

Section 208 amends section 3(c)(3) of the Act by adding new subparagraph (B). New subparagraph (B) requires the Administrator, as expeditiously as possible, to review and act on any application that (1) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; or (2) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data. This amendment would not alter in any way the criteria for approval of an application, but would simply provide for expedited review.

In expediting such applications, the Administrator must notify the registrant whether the application is complete wi hin 45 days after receiving the application and whether the application is granted or denied within 90 days after receiving a complete application. If the application is denied, the Administrator must notify the registrant in writing of the specific reasons for the denial.

Section 209—Notice of application

Section 209 amends section 3(c)(4) of the Act to require the Administrator to publish notice of an application for the registration

of a pesticide not later than 30 days after receipt and provide a 60-day comment period on the application. Section 3(c)(4) currently requires that a notice of application be published "promptly" and provides for a 30-day comment period.

Section 210—Denial of registration

Section 210 amends section 3(c)(6) of the Act to provide that, if the Administrator issues a notice of the denial of registration, a request for a hearing under section 6 of the Act (as authorized under current law) must be made within 30 days after receipt of the notification. The Administrator may issue regulations governing the right to a hearing with respect to the denial of any application for the registration of a product containing an ingredient that was canceled under section 6. Under the regulations, due weight must be given to the desirability of the finality of prior proceedings and determinations, and the extent that the applicant had an opportunity to participate in earlier proceedings.

Section 211—Registration under special circumstances

Section 211 amends section 3(c)(7)(A) of the Act to clarify that an applicant seeking conditional or amended registration may cite, as well as submit, required data.

Section 212—Conditional registration

Section 212 amends subparagraphs (B) and (C) of section 3(c)(7) of the Act regarding conditional registrations.

New subparagraph (B) contains a provision, like current law, authorizing the Administrator to conditionally amend the registration of a pesticide to permit additional uses of the pesticide, notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (1) the applicant has submitted or cited the additional data required solely for the proposed additional use; and (2) amending the registration in the manner proposed by the applicant would not materially increase the risk of any unreasonable adverse effect on the environment. However, new subparagraph (B) would add a third requirement for the conditional registration—that the additional use is in the public interest.

New subparagraph (B), like current law, further provides that no registration may be amended to permit an additional food or feed use of a pesticide during the pendency of any evaluation by the Administrator that was initiated by a notice stating that the pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure and specified in regulations issued under the provisions of the Act [section 3(c)(8)] relating to special reviews. The Administrator may amend the registration of the pesticide to add a minor food or feed use, notwithstanding that a notice has been issued that the pesticide may meet or exceed the risk criteria, if the Administrator determines, with the concurrence of the Secretary of Agriculture, that there is no effective alternative pesticide available that does not meet or exceed the risk criteria.

New subparagraph (B), similar to current law, requires an applicant seeking an amended registration to submit or cite data that

would be required to obtain a registration of a similar pesticide under the Act. If the applicant is unable to submit or cite an item of data because it has not yet been generated, the Administrator may amend the registration of the pesticide under conditions that require the submission or citation of the data no later than would be allowed for the maintenance of the registration of the similar pesticide under the Act.

New subparagraph (B) contains a provision not in current law that, if data concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, or teratogenicity are required to support the registration of a pesticide, and if a reasonably sufficient period of time has elapsed for the generation and submission of the data since the data requirement was first imposed, a conditional amendment to permit an additional use of the pesticide for other than a minor use may not be granted unless the data have been submitted.

New subparagraph (C) restates current provisions of law to allow the Administrator to conditionally register a pesticide containing an active ingredient not contained in any registered pesticide for a period of time reasonably sufficient for generation and submission of required data. This provision applies to data that have not been submitted because a period of time reasonably sufficient for the generation of the data has not elapsed since the data requirement was imposed. Any such registration is subject to the conditions that (1) by the end of the period the Administrator receives the data and the data do not meet or exceed risk criteria associated with human dietary exposure specified in regulation under the provision of the Act (section 3(c)(8)) relating to special reviews; and (2) other conditions that the Administrator may prescribe. A conditional registration may be granted only if the Administrator determines that use of the pesticide during the period will not cause any unreasonable adverse effect on the environment and that use of the pesticide is in the public interest. If data concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, or teratogenicity would be required for registration of the pesticide and a period reasonably sufficient for generation of such data has elapsed since the data requirement was first imposed by the Administrator, then such conditional registration of the pesticide may not granted unless the data have been submitted.

Section 213—Public interim administrative review

Section 213 amends paragraph (8) of section 3(c) of the Act, which provides for public interim administrative reviews. This section codifies existing procedure and policies regarding reviews.

Subparagraph (A) of new paragraph (8) provides that, in general, a public interim administrative review to determine whether the use of a pesticide (including a category of pesticides) may pose unreasonable adverse effects to humans or the environment must be conducted in accordance with new paragraph (8).

Subparagraph (B) of new paragraph (8) requires the Administrator to set forth, in published regulations, the criteria for initiating a public interim administrative review. The criteria must be based on levels of risk and could include consideration of currently available exposure data. The absence of exposure data must not delay or

preclude initiation of a public interim administrative review. The Administrator may decline to initiate a review solely on the basis of exposure only if adequate data on all relevant means of exposure have been considered.

Subparagraph (C) of new paragraph (8) restates existing law, which provides that the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of ingredients of a pesticide or any of its uses before initiating a formal action to cancel, suspend, or deny the registration of the pesticide under the Act unless the public administrative review process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment.

Subparagraph (D) of new paragraph (8) provides that, on receipt of information about a pesticide demonstrating that the criteria for initiating a public interim administrative review have been met, the Administrator must immediately notify all registrants of the pesticide and provide the registrants with appropriate information and an explanation of the manner in which the criteria have been met. Not later than 30 days after receipt of the notice, a registrant may respond to the notice. Not later than 60 days after the Administrator provides a notice, the Administrator must determine whether a public interim administrative review of the pesticide will be initiated.

Subparagraph (E) of new paragraph (8) requires that, if the Administrator intends to initiate a public interim administrative review of a pesticide registered for agricultural uses, the Administrator must notify the Secretary of Agriculture of the intention to initiate the review and the reasons for the review.

Subparagraph (F) of new paragraph (8) establishs procedures for the public interim administrative review. Any public interim administrative review must be initiated and conducted in accordance with regulations published by the Administrator. The regulations must provide that a public interim administrative review include a notice of initiation of the review and opportunity for public comment on the notice, a notice of the Administrator's preliminary determination and opportunity for public comment thereon, and a notice of final determination. The Administrator may combine or forgo any of the above notices. Any proposed determination of the Administrator must be submitted to the Scientific Advisory Panel at its next scheduled meeting for comment solely on relevant scientific issues. Any member of the public may submit comments to the Scientific Advisory Panel on the scientific issues.

Under subparagraph (F), the notice of the initiation of a public interim administrative review or the notice of preliminary determination must state the basis for the review or determination and include a request for any additional data needed, and a bibliography of all scientific data and studies, and expert analyses, concerning the risks or benefits of the pesticide that are under review. Information in the bibliography must be made available to the public consistent with the trade secrets provisions of the Act. The Administrator must determine, to the extent feasible, before the initiation of the review which data in the bibliography could be disclosed to the public under the Act. If the Administrator receives additional

data concerning the risk or benefits, the bibliography must be revised within 30 days and made available to the public.

Not later than 90 days after the publication of the notice of the initiation of a public interim administrative review or a notice of preliminary determination, comments may be submitted on the review or determination. Any person who submits comments must disclose to the Administrator all scientific data and studies, and analyses, in the person's possession concerning the risks or benefits of the pesticide that are under review that were not included in the bibliography in the notice. New scientific data, studies, and expert analyses of the data must be disclosed to the Administrator by such person within 30 days after he receives them.

Subparagraph (F) requires the Administrator to decide, not later than 18 months after the initiation of the review, which regulatory action (if any) to take and publish the decision.

The time limits specified for the review may not be extended, except in the exceptional circumstances in which (1) additional data critical to a fair and accurate determination of risks posed by the pesticide are required; (2) the extension is for a period limited to the time required to obtain the data on an expedited basis and in no event to exceed one year; and (3) the Administrator acted to obtain the additional data at the time the public interim administrative review was initiated unless the Administrator could not have reasonably known of the need for the data at that time.

Subparagraph (G) of new paragraph (8) allows any person to seek judicial review under section 16(a) of the Act for failure of the Administrator to act within a required time period.

Section 213(b) provides that the amendments made to section 3(c)(8) apply only to reviews initiated after 1 year after date of enactment.

Section 214—Preregistration access to data

Section 214 adds a new paragraph (9) to section 3(c) of the act, to provide the public access to data submitted to the Administrator to support applications for pesticide registrations.

Subparagraph (A) of new paragraph (9) requires the Administrator to provide public access to health, safety, and environmental data that are submitted or cited in support of an application for the registration of a pesticide containing a new active ingredient or an application for the registration of a pesticide to authorize the initial food use of a previously registered pesticide. The data must be accessible during the period prior to the Administrator's action on the application.

Subparagraph (B) of new paragraph (9) provides that, to obtain access to the preregistration data, a person must send a request for access and the affirmation described below simultaneously to the Administrator and the registration applicant by certified mail, not later than 30 days after the Administrator publishes a notice of the application for registration.

Subparagraph (C) of new paragraph (9) provides that the Administrator must grant the request for access to the data unless, within 15 days after the administrator's receipt of the request and the required affirmation, the applicant submits an objection asserting that the affirmation is inaccurate and the reasons for the objection.

The Administrator must determine whether or not to grant the request within 5 days of receipt of a timely objection. If the request is granted access must not be permitted until 5 days after the applicant making objection has been notified that access has been granted. If the Administrator denies access to the data, comments on the application for which the data were submitted or cited must be filed within 60 days after the date of the decision denying access.

Subparagraph (D) of new paragraph (9) provides that the preregistration data may be made available only to a person who provides an affirmation, and supporting evidence that the Administrator considers necessary, that the person is not engaged in the production, sale, or distribution of a pesticide, and is neither employed by nor acting directly or indirectly on behalf of a person (or affiliate thereof) engaged in the production, sale, or distribution of a pesticide. The affirmation must identify any business, employer, or other person, if any, on whose behalf the person is requesting the access to data, and state that the person will not intentionally or recklessly violate these provisions. An affiliate of a person is defined as a person who directly or indirectly, through one or more intermediaries, controls or is controlled by or is under common control with the other person. Penalties under section 1001 of title 18 of the United States Code will apply to false statements made in the affirmation.

Subparagraph (E) of new paragraph (9) provides that data supporting an application for registration may be made available to a person only for the purpose of permitting the person to comment to the Administrator on the application. Comments submitted to the Administrator may reasonably quote the data, but no person, including the Administrator, may make the comments public prior to a decision by the Administrator on the application for registration (or after the decision if the application is denied). Except as described below in this paragraph, a person who obtains data under new paragraph (9) (directly or indirectly) may not publish, copy, or transfer the data to any other person for use to obtain approval to sell, manufacture, or distribute a pesticide anywhere in the world, or use the data for any purpose before any court or government agency prior to the Administrator's decision to approve the registration (or after the decision, if the application for registration is denied). Preregistration data and comments may be disclosed, consistent with provisions of the Act that protect trade secrets and other information, after registration of the pesticide.

Subparagraph (F) of new paragraph (9) provides that the preregistration data may be examined at an office of the Environmental Protection Agency or an appropriate State agency under the conditions prescribed by the new paragraph (9), but could not be removed from the office. The Administrator must maintain a record of the persons who inspect the data and a copy of this record must be sent to the data submitter upon request.

Subparagraph (G) of new paragraph (9) provides that, once access to preregistration data is granted, the data may be examined and notes on the data could be taken for use in developing comments on the application for registration. Comments on the application must be filed within 60 days after the decision of the Administrator

granting access, unless the comment period is extended an additional 30 days by the Administrator for good cause.

Section 215—Classification of pesticides

Section 215 amends section 3(d)(1) of the Act to clarify that pesticides may be reclassified by regulations, and to clarify the Administrator's authority to regulate the use of restricted pesticides.

Section 216—Disclosure of certain ingredients

Section 216 amends section 3(f) by adding new paragraph (4). New paragraph (4) provides that in regulating the in-plant application of a wood preserving pesticide under the Act, the Administrator must, by label requirement, assure that excess quantities of the pesticide that are collected and contained to be reapplied by the same user in the wood preserving process must be regulated as a pesticide.

This section covers the in-plant containment, collection and reapplication of excess pesticide during wood preserving applications only. It is not the intent of the Committee to regulate other activities that are outside the framework of the process of collecting, containing and reapplying pesticides within a wood preserving facility. Excess amounts of pesticide that are collected and contained in a device or system specifically designed to collect drippage so as to prevent contamination and are reapplied by the same user within a reasonable period of time in the wood preserving process shall be treated as a pesticide. Any drippage that is spilled onto the soil is no longer considered a pesticide. The committee wishes to encourage the wood preserving industry to construct or retrofit facilities designed to minimize the routes of contact between the pesticide and soil, surface water or ground water. This section does not affect existing authorities under other laws, including the Resource Conservation and Recovery Act 1976 or the Comprehensive Environmental Response Compensation Liability Act.

Section 217—Priority list and data requirements for inert ingredients

Section 217 amends section 3 of the Act by adding a new subsection (g) to direct the Administrator to establish a priority list of: (1) inert ingredients that appear to cause a pesticide to meet or exceed a criterion for initiating a public interim administrative review under the Act; (2) inert ingredients for which additional data are reasonably necessary to assess the risk that the inert ingredient may result in a pesticide causing an unreasonable adverse effect on the environment, that are similar in molecular structure to a chemical that is oncogenic, mutagenic, or teratogenic or causes another similarly significant adverse effect, and that have significant use in pesticides or to which there is significant exposure from pesticides; and (3) inert ingredients for which additional data are reasonably necessary to assess the risk that he inert ingredient may result in a pesticide causing an unreasonable adverse effect on the environment, if the pesticide is one to which there is significant exposure. In establishing the priority list, the Administrator must take into account the differences in concept, usage, and environmental risks between various classes of pesticides; and data for

evaluating the risks between agricultural and nonagricultural pesticides.

The priority list must be published by the Administrator not later than 90 days after the effective date of the bill. Revisions to the list must be published annually. The priority list, any inert ingredient's inclusion on or exclusion from the list, or any revision to the list is not subject to judicial review.

The priority list must consist of not less than 50 inert ingredients unless the Administrator determines that there are fewer than 50 inert ingredients that meet the requirements for inclusion on the list. The list may not exceed 75 inert ingredients.

New subsection (g) also requires the Administrator to determine whether additional data are required for an inert ingredient in a registered pesticide not later than 1 year after the inert ingredient is placed on the priority list described above. Section 217 provides that the Administrator must require each registrant of the pesticide, or manufacturer or processor of the inert ingredient under the Toxic Substances Control Act, to submit the data. The data must be submitted within a reasonable time but not later than four years after the request, unless the Administrator extends the period by not more than two years if extraordinary circumstances beyond the control of the registrant or producer prevent the submission of the data. Data requirements imposed, or a decision not to require data for an inert ingredient, are subject to judicial review under procedures provided in section 16(b) of the Act.

On receipt of additional data the Administrator must, within one year, evaluate the data and take appropriate steps to prevent unreasonable adverse effects on the environment caused by pesticides that contain the inert ingredient. Under exceptional circumstances, the Administrator may extend the evaluation period by not more than one year.

New subsection (g) states that it is not to be construed to affect any other authority of the Administrator to regulate impurities, contaminants, degradants, or other ingredients of pesticides that have been deliberately added; to regulate any deliberately added inert ingredient that has not previously been used in a pesticide, or a significant new use of the inert ingredient in a pesticide; to require the submission of short-term environmental fate or residue studies for deliberately added inert ingredients; or to require the submission of revised formula statements under section 3(c)(2)(B) of the Act.

Section 218—Antimicrobial standards

Section 218 amends section (3) of the Act by adding a new subsection (h). New subsection (h) requires the Administrator to establish efficacy standards for antimicrobial control agents (including disinfectants) used to control pest microorganisms that pose a threat to human health, including standards for disinfectants used in hospitals and other health care facilities. The Administrator also must conduct, or require to be conducted, representative monitoring (including testing) of the compliance of the agents with the standards; and implement an enforcement program under which the agents must comply with standards or be prohibited from sale of distribution as an antimicrobial agent.

The term "efficacy," is defined as "the capacity of an antimicrobial control agent (including a disinfectant) to produce the desired effect or the effectiveness of such an agent." New subsection (h) takes effect 60 days after the date of enactment of the bill.

Section 219—Neurotoxicological and behavioral effects testing

Section 219 amends section (3) of the Act by adding new subsection (i). New subsection (i) requires the Administrator to develop methods for testing to accurately detect neurotoxicological and behavioral effects of pesticides and pesticide ingredients, and as such methods are developed, requires to the extent appropriate and necessary, that data from such testing be submitted by persons seeking to obtain or maintain registrations.

In light of recommendations by the National Academy of Sciences, National Center for Toxicological Research, and the World Health Organization for expanded neurobehavioral and behavioral testing, the bill directs EPA to require testing methods that can detect whether pesticides and their active or inert ingredients may be neurotoxic or adversely affect behavior. After methods are developed, the Administrator must issue regulations requiring registrants to submit data from such tests. Testing should be sufficiently comprehensive to accurately detect pesticides that have the potential to be neurotoxic.

TITLE III—REREGISTRATION OF PESTICIDES

Section 301—Reregistration of registered pesticides

Section 301 adds, after section 3 of the Act, a new section 3A to provide for the reregistration of pesticides. New section 3A requires the Administrator to reregister approximately 600 pesticide active ingredients that were approved for use before November 1, 1984, to determine whether the ingredients meet contemporary health and safety requirements. Current law requires that pesticides be reregistered, but provides no guidance, deadline, or specific resources for EPA to finish the process. Under new section 3A, reregistration is to be completed in five phases over nine years. When the reregistration deadline is reached, the Agency is to have fully analyzed each product to determine whether the standards under section 3(c)(5) have been met. Those products that meet the standards should be reregistered; those that do not meet the standards should be proposed for cancellation or other appropriate action under section 6.

Subsection (a) of new section 3A provides a general rule requiring the Administrator to reregister, in accordance with new section 3A, each registered pesticide containing any active ingredient contained in any pesticide first registered before November 1, 1984, except for any pesticide that the Administrator had determined after November 1, 1984, and before the effective date of these provisions, that there are no outstanding data requirements and the other requirements for registration under the Act have been met.

Subsection (b) of new section 3A requires the Administrator, not later than one year after the date of enactment of the bill, by order, to issue guidelines to be followed by registrants in summarizing studies, reformatting studies, identifying adverse information,

and identifying studies that have been submitted that may not meet the registration requirements of the Act or its regulations. The guidelines are not subject to judicial review. The Administrator must monitor the progress of registrants in acquiring and submitting data required by section 3A

New subsection (b) also establishes penalties for certain violations of new section 3A. It requires the Administrator to issue a notice of intent to suspend the registration of a pesticide, in accordance with the procedures provided by section 3(c)(2)(B) of the Act, if the Administrator determines that progress is insufficient to ensure the submission of the data required under a commitment within the time period required under section 3A, or if the registrant fails to submit the data within the time period. A notice of intent to suspend also must be issued if the Administrator determines that tests necessary to fill an outstanding data requirement have not been initiated within one year after the issuance of a notice for additional data under section 3A. If the administrator determines that progress is insufficient to ensure submission of the data necessary to fill an outstanding data requirement within the prescribed time period or if the required data have not been submitted to the Administrator within the time period, the Administrator must issue a notice of intent to suspend the registration. The Administrator also must issue notice of intent to suspend if a registrant otherwise fails to comply with the provisions of section 3(c)(2)(B), which relate to how registrants are to provide additional data to support an existing registration.

A registrant who submits a false certification under subsection (b) of new section 3A must be considered to have violated the Act and be subject to the civil and criminal penalties under section 14 of the Act.

Subsection (c) of new section 3A provides an outline of the phases of reregistration under section 3A:

Phase one includes the listing of the active ingredients of pesticides that must be reregistered.

Phase two requires the submission to the Administrator by registrants of (1) notices respecting their intention to seek reregistration; (2) identification of missing and inadequate data; and (3) commitments to replace the missing or inadequate data within the applicable time period.

Phase three includes the submission of certain information supporting the reregistration of the pesticide

Phase four includes an independent initial review by the Administrator of the submission required under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, of requirements to submit additional data.

Phase five includes the review by the Administrator of data submitted for reregistration and appropriate regulatory action by the Administrator.

Subsection (d) of new section 3A provides for phase one the reregistration of pesticides. Under these provisions, the Administrator lists the active ingredients of pesticides to be reregistered giving priority to active ingredients (other than active ingredients of pesticides for which registration standards have been issued before the date of enactment of the bill) that, among other things: (1) are in

use on or in food or feed and may result in postharvest residues; (2) may result in residues of potential toxicological concern in potable ground water, edible fish, or shellfish; (3) have been determined by the Administrator before the date of enactment of the bill to have significant outstanding data requirements; or (4) are used on crops, including greenhouses and nurseries, where worker exposure is most likely to occur.

Pesticides that already have been assigned reregistration requirements are presumably far along in the reregistration process. They are to be reregistered according to time schedules set out in EPA regulations, which should not and may not exceed the maximum reregistration deadlines allowed in the bill.

Subsection (d) requires the Administrator, by order, (1) not later than 70 days after the date of enactment of the bill, to list pesticide active ingredients for which registration standards have been issued; (2) not later than 4 months after date of enactment, to list the first 150 pesticide active ingredients from the priority list described above; (3) not later than 7 months after date of enactment, to list the second 150 of the pesticide active ingredients from the priority list; and (4) not later than 10 months after date of enactment, to list the remainder of the pesticide active ingredients from the priority list. Each of the lists must be published in the Federal Register. The content of the lists would not be subject to judicial review under section 16 of the Act.

The Administrator must notify, by certified mail, registrants of pesticides that contain active ingredients that are published on a list at the time of publication. This notice would specify when registrants must notify the Administrator of their intention to seek or not to seek reregistration.

Subsection (e) of new section 3A, phase two of reregistration, provides, as general rule, that each registrant of a pesticide that contains an active ingredient listed for reregistration, and not included on the list of pesticide active ingredients with registration standards, must (within the time period described below) submit a notice of intent to seek or not to seek reregistration and any information, commitment, or offer, as described below.

NOTE.—Pesticide active ingredients with registration standards would be listed separately and would not be subject to all of the requirements under the preliminary phases of section 3A.

Specifically, the registrant must notify the Administrator by certified mail whether or not the registrant intends to seek reregistration of the pesticide. If the registrant notifies the Administrator of an intention not to seek reregistration, the Administrator must publish a notice of this fact in the Federal Register. A registrant must notify the Administrator within three months after the publication of the list that includes the active ingredient. The Administrator could extend this period if factors beyond the control of registrant prevent compliance with the period prescribed.

Subsection (e) provides that each such registrant who submits a notice of intention to seek reregistration must submit, in accordance with regulations issued under the registration provisions of the Act, an identification of (1) all data required to support registration with respect to the active ingredient, (2) data previously submitted by the registrant in support of the registration of the

pesticide that are inadequate, and (3) data not submitted but required for reregistration.

In addition, the registrant must submit either (1) a commitment to replace or submit the inadequate or missing data within a reasonable time determined by the Administrator, but not more than 48 months, or (2) an offer to share in the cost to be incurred by a person who has made a commitment to replace or submit the data and an offer to submit to arbitration under section 3(c)(2)(B) of the Act with regard to sharing in the cost of the data. (An additional 2 years may be allowed in extraordinary circumstances, such as where the Administrator conditioned the required submission of exposure or benefits data on the results of the toxicological data.)

Subsection (e) provides that data are inadequate for the above purposes if the data are derived from a study with respect to which the registrant is unable to make a certification that the registrant possesses or has access to the raw data used in or generated by the study. Further, data will be considered to be inadequate if the data are derived from a study submitted before January 1, 1970, unless it is demonstrated to the satisfaction of the Administrator that the data should be considered to support the registration of the pesticide.

Subsection (e) also provides sanctions for registrants that do not comply with its requirements. If a registrant does not submit a notice of intention to seek or not seek reregistration not later than 3 months after the listing of the pesticide active ingredient, the Administrator must issue a notice of intent to cancel the registration of the registrant for the pesticide. The notice of intent to cancel must be published in the Federal Register and 60 days allowed for comments. After such time, the Administrator, by order and without further hearing, may cancel their registration or take other action, including extension of the time period, as may be needed to allow the reregistration of the pesticide by another person.

If no registrant of a pesticide containing an active ingredient listed for reregistration notifies the Administrator that the registrant intends to seek reregistration of any pesticide containing that active ingredient, or if no registrant complies, as required under phase two, with the requirements for identification of missing or inadequate data, had submissed a commitment to replace the missing or inadequate data within the applicable time period, then the Administrator must publish in the Federal Register a notice of intent to remove the active ingredient from the reregistration list and a notice of intent to cancel the registrations of all pesticides containing the active ingredients. The Administrator must provide 60 days for comments on the notice. After the 60-day comment period, the Administrator, by order, may cancel any of the registrations without a hearing. However, the Administrator may not cancel a registration under this provision if, during the comment period, a person acquires the registrant's rights in the registration and furnishes a notice of intent to reregister the pesticide, and not later than 120 days after publication of the notice of intent to cancel, the person complies with the other requirements of phase two and pays the reregistration fee.

Subsection (f) of new section 3A provides for phase three of reregistration. Each registrant who has submitted, under phase two, a

notice of intent to seek the reregistration of a pesticide active ingredient listed for reregistration, not including pesticide active ingredients with registration standards, must submit within 12 months after listing and in accordance with the guidelines issued by the Administrator—

(1) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing the active ingredient and considered by the registrant to be adequate to meet the requirement of the registration provisions of the Act and its regulations, and a certification that the registrant possesses or has access to the raw data used in or generated by the studies;

(2) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing the active ingredient that may not comply with the registration provisions of the Act and its regulations, but that the registrant asserts should be deemed to comply with the regulations, and a certification that the registrant possesses or has access to the raw data used in or generated by the studies;

(3) a reformat of the data from each study summarized as described above concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, or teratogenicity, or residue chemistry of the active ingredient that were submitted to the Administrator before January 1, 1982;

(4) where data that are to be reformatted are not required for the active ingredient by the regulations issued under the registration provisions of the Act, a reformat of acute and subchronic dosing data submitted by the registrant before January 1, 1982, that the registrant considers to be adequate to meet the requirements of the registration provisions of the Act and its regulations;

(5) an identification of data that are required to be submitted to the Administrator as indicating an adverse effect of the pesticide under proposed new secion 6(g)(4) of the Act, to be added by section 305 of the bill;

(6) an identification of any other information available that in the registrant's view supports the registration;

(7) either a commitment to submit data to fill each outstanding data requirement identified by the registrant, within a reasonable period of time determined by the Administrator but not more than 48 months (unless the Administrator extends this period by not more than two years if extraordinary circumstances beyond the control of the registrant prevent compliance with the 48-month period), or an offer to share in the cost of developing the date to be incurred by a person who has made a commitment to submit the data and an offer to submit to arbitration under section 3(c)(2)(B) of the Act with regard to cost sharing; and

(8) evidence of compliance with the data compensation provisions of the Act and its regulations with regard to previous submitted data as if the registrant were now seeking the original registration of the pesticide.

Subsection (e) provides sanctions for registrants that fail to comply with the requirements of phase three. If the registrant of a pesticide fails to submit the information required under phase three within the prescribed time period, the Administrator, by order and without hearing, must cancel the registration of the pesticide.

If the registrant submits the phase three information within the time period prescribed, but the information does not conform to the guidelines for submissions established by the Administrator, the Administrator must determine whether the registrant made a good-faith attempt to conform to the guidelines. If the Administrator determines that the registrant made a good-faith attempt to conform to the guidelines, the registrant will be provided a reasonable time to make necessary changes or corrections. If the Administrator determines that the registrant did not make a good-faith attempt to conform, a notice of intent to cancel the registration would be issued, and sent to the registrant by certified mail. The registration will be canceled without a hearing or further notice 30 days after the registrant receives the notice, unless a hearing is requested by the registrant. A hearing must be conducted under the hearing provision of section 6(d) of the Act, except that the only matter for resolution at the hearing would be whether the registrant made a good-faith attempt to conform its submission to the guidelines. The hearing must be held and a determination made within 75 days after the receipt of the request for a hearing.

Subsection (g) of new section 3A provides for phase four of reregistration. The Administrator must review the submissions of all registrants made under phases two and three of reregistration with regard to an active ingredient to determine if all data concerning that ingredient that are missing or inadequate were identified. The Administrator may require registrants to submit complete copies of studies summarized under phase three.

Subsection (g) also requires the Administrator to independently identify and publish in the Federal Register the outstanding data requirements for each active ingredient listed under phase one that is contained in a pesticide to be reregistered (other than any pesticide active ingredient for which registration standards have been issued). The Administrator, at the same time, must issue notice under section 3(c)(2)(B) of the Act to require the submission of additional data necessary to meet the outstanding data requirements. The Administrator must take the actions required under phase four, in the case of a pesticide containing an active ingredient without a registration standard, listed under phase one in the first group of 150, not later than 18 months after the date of the listing. For a pesticide containing an active ingredient without a registration standard, listed under phase one in the second group of 150, the Administrator must take the actions required under phase four not later than 24 months after the date of listing. In the case of a pesticide containing an active ingredient without a registration standard, listed under phase one in the last group of active ingredients to be reregistered, the Administrator must take the actions required under phase four not later than 33 months after the date of the listing.

New subsection (g) provides that, if the Administrator issues a notice to a registrant under phase four for the submission of additional data, the registrant must submit the data within a reasonable period of time determined by the Administrator (but not to exceed 48 months after issuance of the notice). The Administrator, on application of a registrant, may extend this period by no more than two years if extraordinary circumstances beyond the control of the registrant prevent compliance with the prescribed period.

Subsection (h) of new section 3A provides for phase five of reregistration. Under subsecton (h), the Administrator must conduct a thorough examination of all data submitted under the reregistration provisions for each active ingredient, and all other available data found by the Administrator to be relevant. Within one year after the submission of all data concerning an active ingredient submitted under subsection (g), the Administrator must determine whether pesticides containing the active ingredient are eligible for registration. For extraordinary circumstances, the Administrator may extend such period for up to one additional year.

Before reregistering a pesticide, the Administrator must obtain any needed product-specific data regarding the pesticide by use of section 3(c)(2)(B). The Administrator must require that the product-specific data be submitted not later than eight months after it is determined that a pesticide is eligible for reregistration, unless the Administrator determines that a longer period is required for generation of the data. The Administrator then must review such data within 90 days after its submission.

Under subsection (h), after conducting the required reviews, the Administrator must determine whether to reregister a pesticide by determining if the pesticide meets the registration requirements of the Act. If the Administrator determines that a pesticide is eligible to be reregistered, then it must be reregistered within six months following the date all required product-specific data were submitted for the pesticide. If after conducting the required reviews the Administrator determines that a pesticide should not be reregistered, the Administrator must take appropriate regulatory action.

Subsection (i) of new section 3A contains provisions for compensation of persons who submit data data under section 3A for use of such data. Subsection (i) provides that the existing data compensation provisions of section 3 of the Act will apply to data submitted by a registrant under phases two through five that are used to support the application for registration of another person under section 3. In determining the amount of compensation, fees paid by the registrant for reregisteration must be taken into account.

Subsection (j) of new section 3A provides for one-time reregistration fees based on active ingredients and annual registration maintenance fees.

Under paragraph (1) of subsection (J), the registrants of pesticides that contain an active ingredient that is listed under under subparagraph (B), (C), or (D) or subsection (d)(2) and that is an active ingredient of any pesticide registered for a major food or feed use must collectively pay an initial fee of $50,000 on submission of information under paragraphs (2) and (3) of subsection (e) (phase two of reregistration) for such ingredient.

Under paragraph (2)(A) of subsection (j), the registrants of pesticides that contain an active ingredient described in the preceding paragraph collectively must pay a final fee of $100,000 on submission of information for such ingredient under subsection (f)(1) if data are reformatted under subsection (f)(1)(C) or on submission of data for such ingredient under subsection (f)(2)(B) if data are not reformatted under subsection (f)(1)(C) (phase three of reregistration).

Under paragraph (2)(B), the registrants of pesticides that contain an active ingredient for which a registration standard has been issued and that is an active ingredient of any pesticide registered for a major food or feed use must collectively pay a fee of $150,000 at such time as the Administrator prescribes.

Paragraph (3)(A) of subsection (j) states that the registrants of pesticide that contain an active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (d)(2) and that is not an active ingredient of any pesticide registered for a major food or feed use must collectively pay fees in amounts determined by the Administrator. Such fees may not be less than one-half of, nor greater than, the fees required by paragraphs (1) and (2). A registrant must pay such fees at the times corresponding to the times fees prescribed by paragraphs (1) and (2) are to be paid.

Paragraph (3)(B) of subsection (j) states that the registrants of pesticides, that contain an active ingredient for which a registration standard has been issued and that is not an active ingredient of any pesticide that is registered for a major food or feed use, shall collectively pay a fee of not more than $100,000 and not less than $50,000 at such time as the Administrator prescribes.

Paragraphs (4)(A) and (B) of subsection (j) provide an exemption from the reregistration fees described in paragraph (3) for (1) an active pesticide of a pesticide that is registered solely for an agricultural or nonagricultural minor use, or a pesticide the value or volume of use of which is small, or (2) an antimicrobial active ingredient, the production level of which does not exceed 1,000,000 per year.

Paragraph (4)(C) provides for a registration fee waiver for small business registrants. If during the 3-year period prior to the reregistration, the average annual gross revenue of the registrant from the pesticides containing an active ingredient is less than $5,000,000, the registrant must pay 0.5 percent of such revenue; is $5,000,000 or more but less than $10,000,000, the registrant must pay 1 percent of such revenue; or is $10,000,000 or more, the registrant must pay 1.5 percent of such revenue, but not more than $150,000.

A small business registrant is a corporation, partnership, or unincorporated business that has 150 or fewer employees and during the 3-year period prior to registration had an average annual gross revenue from chemicals that did not exceed $40,000,000.

Paragraph 5 of subsection (j) provides for annual registration maintenance fee to be paid by March 1 for a period of nine years. A registrant holding not more than 50 pesticide registrations must pay an annual fee of $425 for each registration. A registrant holding more than 50 registrations must pay $425 for each registration up to 50 registrations and $100 for each registration over 50 regis-

trations, except that no fee is charged for more than 200 registrations held by any registrant.

Subparagraph (N) states that the amount of each fee prescribed under subparagraph (A) must be adjusted by the Administrator to a level that will result in the collection under this paragraph of, to the extent practicable, an aggregate amount of $14,000,000 each fiscal year.

Subparagraph (C) states that the maximum annual fee payable by a registrant holding not more than 50 registrations shall be $20,000, and that the maximum annual fee payable by registrant holding more than 50 registrations shall be $35,000.

Subparagraph (D) provides that if any fee prescribed by this paragraph, with respect to the registration of a pesticide, is not paid by a registrant by the time prescribed, the Administrator, by order and without hearing, may cancel the registration.

Subparagraph (E) states that the authority provided to assess maintenance fees under this paragraph shall terminate on September 30, 1997.

Paragraph (6) provides that the Administrator may not levy any other fees for the registration of a pesticide under the Act except as provided in paragraphs (1) through (5) during the period beginning on the date of enactment of this section and ending on September 30, 1997.

Paragraph (7) provides that if two or more registrants are required to pay any fee prescribed by paragraph (1), (2), or (3) with respect to a particular active ingredient, the fees for such active ingredient must be apportioned among such registrants on the basis of the market share in United States sales of the active ingredient for the three preceding calendar years, except as follows. Small business registrants that produce the active ingredient must pay fees as described above. Registrants who have no market share but who choose to reregister a pesticide containing the active ingredient must pay the lesser of 15 percent of the fees or a proportionate fee based on the lowest percentage market share held by a registrant active in the market. Such registrants may not collectively pay more than 25 percent of the total active ingredient reregistration fee.

The Administrator, by order, may require a registrant to submit a report to allow the Administrator to apportion fees or to determine a registrants eligibility for a reduction or waiver of a fee.

If any required apportionment report is not submitted by a registrant after receiving notice, or if any fee is not paid by the prescribed time, the Administrator, by order and without hearing, may cancel each registration held by the registrant of a pesticide containing the active ingredient involved. The Administrator then must reapportion the fee among the remaining registrants and notify the registrants that they are required to pay any unpaid balance of the fee within 30 days after receipt of the notice.

Subsection (k) of new section 3A provides that the requirements of phases two, three, and four and the reregistration fee requirements of section 3A will not apply to any person who is the registrant of a pesticide to the extent that, under the exemption provided under section 3(c)(2)(D) of the Act, the person would not be required to submit or cite data to obtain an initial registration of the

pesticide under section 3. The exemption does not apply to maintenance fees under paragraph (5) of subsection (j).

Subsection (1) of new section 3A establishes in the Treasury of the United States a reregistration and expedited processing fund. All fees collected by the Administrator under subsection (j) must be deposited into the fund and be available to the Administrator, without fiscal year limitation, to carry out section 3 of the Act and subsection (1)(3).

Subsection (1)(3) requires the Administrator to use each fiscal year not more than $2,000,000 of the amounts in the fund to obtain sufficient personnel and resources to assure the expedited processing and review of any application that (1) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in compostion and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from any such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; or (2) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data. Any such amounts made available must be used to obtain sufficient personnel and resources to carry out the activities described that are in addition to those available to carry out such activities on the date of enactment of this section.

Money in the fund not currently needed to carry out this section must be maintained on hand or on deposit, invested in obligations of, or guaranteed by, the United States, or invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds. The Administrator must provide an annual accounting of the fees collected and disbursed from the fund and take all steps necessary to ensure that the expenditure of the funds are used only to carry out the reregistration provisions.

Subsection (m) of new section 3A provides that any failure of the Administrator to take any action required under the reregistration provisions of section 3A will be subject to judicial review under section 16(b) of the Act.

TITLE IV—CERTIFICATION AND TRAINING

Section 401—Certification, training, and recordkeeping amendments

Section 401 amends section 4 of the Act (which deals with the use of restricted use pesticides and the certification of applicators) by adding new subsections (d) through (l).

New subsection (d) provides rules with respect to the training and certification of commercial applicators.

Under paragraph (1) of new subsection (d), it is a violation of the Act for any person to use any pesticide as a commercial applicator unless the person is a certified commercial applicator, or a registered commercial applicator under the direct supervision of a certified applicator who is a certified commercial applicator.

Under paragraph (2) of new subsection (d), to be considered to be a certified commercial applicator, a person must at a minimum—

(1) have met the standards prescribed under subsection (a) of section 4 of the Act and have received training prescribed by the State agency responsible under section 4 for administering using material developed by the Administrator in consultation with the Secretary of Agriculture under new subsection (g) of section 4 that satisfies the minimum standards for training programs under new subsection (h);

(2) have field, institutional, or industrial experience in pesticide use and application;

(3) have passed an examination prescribed by the State agency; and

(4) possess a valid commercial applicator certification issued by the State agency.

Under paragraph (3) of new subsection (d), to operate as a registered commercial applicator, a person at a minimum must have received training prescribed by the State agency (including training using the material developed by the Administrator in consultation with the Secretary of Agriculture under new subsection (g) conducted by a trainer who has met requirements under new subsection (h)), and possess a valid registration by providing to the State agency a report, signed and dated by the trainer and the person who received the training, stating that the prescribed minimum training has been provided and received.

New subsection (e) provides rules with respect to the certification and training of private applicators.

Under paragraph (1) of new subsection (e), a restricted use pesticide must be considered to have been applied by or under the direct supervision of a certified private applicator only if it is applied by a person who is either a certified private applicator, or a supervised private applicator who uses a pesticide under the direct supervision of a certified private applicator.

Under paragraph (2) of new subsection (e), to be considered to be a certified private applicator, a person at a minimum must have (1) met the standards prescribed under subsection (a) of section 4 and have received training prescribed by the State agency (including training using the material developed by the Administrator in consultation with the Secretary of Agriculture under new subsection (g)), conducted by a trainer who has met requirements under new subsection (h), that satisfies the minimum standards for training under new subsection (h), and (2) possess a valid private applicator certification issued by the State agency.

Under paragraph (3) of new subsection (e), to be considered to be a supervised private applicator a person, at a minimum, must have received basic instruction prescribed by the State agency or based on material prescribed by the State agency, including basic instruction material concerning the use of appropriate pesticide application and safety procedure; appropriate clothing and protective equipment for pesticide applications; the detection of common symptoms of pesticide poisoning; the means of obtaining emergency medical treatment; hazards posed by pesticides to workers, the public health, and the environment, and the requirements of applicable laws, regulations and labeling. The training must be given by a certified private applicator, a commercial applicator who is certified in the pest control category appropriate for the instruction

being provided, or a trainer who has met the minimum standards for trainers under new subsection (h). The State agency may require the employer of a supervised private applicator to confirm that the basic instruction described above has been received.

New subsection (f) deals with recertification and reregistration. New subsection (f) requires that certified applicators and registered commercial applicators within a State undergo refresher training and be recertified or reregistered within a period established by the State agency but not to exceed 5 years. The refresher training must be prescribed by the State agency and include training in the materials established by the Administrator in cooperation with the Secretary of Agriculture under new subsection (g) and in the relevant requirements of the other subsections of section 4 and section 3(d) (classification of pesticides), section 12 (unlawful acts), and section 14 (penalties) of the Act. To be recertified, an applicator at the minimum must meet the requirements of paragraph (2) of new subsection (d) (other than the examination requirement) or the requirements of paragraphs (1) and (2) of new subsection (e), as applicable. To be reregistered, a commercial applicator must meet the requirements of paragraph (3) of subsection (d).

New subsection (g) deals with applicator training. New subsection (g) requires the Administrator in consultation with the Secretary of Agriculture to develop training material on the use of appropriate procedures for the application of pesticides, safety procedures for pesticides application, clothing and protective equipment for pesticide application, the detection of common symptoms of pesticide poisoning, the means of obtaining emergency medical treatment, hazards posed by pesticides to workers, the public health, and environment, specific commercial application categories, and the requirements of applicable laws, regulations, and labeling. Within 12 months after the effective date of the bill the Administrator, in consultation with the Secretary of Agriculture, must revise and make current the materials and thereafter update as needed.

New subsection (h) deals with minimum standards for trainers and training materials.

Paragraph (1) of new subsection (h) requires the Administrator to establish, within one year after the effective date of the bill, minimum standards of competency, and experience or expertise, for trainers referred to in new subsection (d), and minimum standards for the training programs referred to in subsection (d). The training programs under subsection (d) must comply with the minimum standards established by the Administrator within two years after the effective date of the standards. If after the two-year period, a State's training program fails to meet the minimum standards, or if a State fails to prescribe the program, the Administrator must notify the State of the failure. After receipt of the notice, a State has 90 days to being its training program into compliance with the standards, after which time, if the program does not meet the standards, the Administrator must prescribe the training programs referred to in subsection (d).

Under paragraph (2) of new subsection (h) the Administrator must establish (within two years after the effective date of the bill) minimum standards of competency, and experience or expertise,

for trainers referred to in new subsection (e), and minimum standards for the training program referred to in subsection (e). Training programs prescribed by any State under subsection (e) must comply with the minimum standards not later than two years after the effective date of the standards. If on the expiration of such two-year period a State's training program fails to meet the minimum standards, or if a State fails to prescribe the program, the Administrator must notify the State of the failure. After receipt of the notice, a State has 90 days to bring its training program into compliance with the standards. If after the 90-day period the State's training program does not meet the standards, the Administrator must prescribe the training programs referred to in subsection (e) for use in the State. In general, it is the intent of the Committee that these amendments should be construed in a manner that encourages the States to employ reciprocity for the satisfaction of training requirements in situations where applicators are applying pesticides in more than one State. Reciprocity among the States should be considered an effective means of achieving a consistently high level for competency while encouraging the free flow of commerce across States lines.

New subsection (i) deals with privately administered training programs. Under new subsection (i), a State agency may approve any privately administered training program that it determines meets the requirements established under section 4, or requirements established by the State agency, whichever are more stringent.

New subsection (j) deals with enforcement officer training. New subsection (j) provides that Federal and State field personnel responsible for on-site observations and inspections of pesticide use must have training that, at a minimum, includes training covering materials specified in new subsection (g) for the commercial application categories for which they are assigned enforcement responsibility.

New subsection (k) provides that in establishing standards under section 4 applicable to applicators, the Administrator must establish separate standards for commercial applicators and private applicators.

New subsection (l) provides that, for the purposes of section 4, the term "State agency" means the agency of a State that is designated in the State certification plan under subsection (a) of section 4 as the agency responsible for administering the plan throughout the State, if the State has primary enforcement responsibility for pesticide use violations as provided for under section 26 of the Act. In the case of a State that does not have primary enforcement responsibility or that does not have an agency designated in the State plan, a reference to a State agency is considered a reference to the Administrator.

The amendments to section 4 made by section 401 must be phased in as follows:

Subsection (d): Except as provided below, the provisions of new subsection (d) must take effect in a State on the expiration of the two-year period prescribed by new subsection (h) (within which training programs of the State are to be in compliance with minimum standards prescribed by the Administrator—which the Ad-

ministrator has one year after the effective date of the bill to establish). If an applicator in a State is certified as a commercial applicator under subsection (a) of section 4 before the effective date described above and the Administrator has determined that the previous certification or recertification requirements in that State do not conform to the requirements of subsection (d), the applicator must be recertified within two yeas after the date the training programs of the State comply with the minimum standards of the Administrator, or within an earlier time as the State may prescribe. The requirements of subsection (d), for registered commercial applicators take effect one year after the expiration of the compliance period prescribed by subsection (h).

Subsection (e): Except as provided below, the provisions of new subsection (e) take effect in a State on the expiration of the compliance period prescribed by subsection (h). If an applicator in a State is certified as a private applicator under subsection (a) before the effective date described above and the Administrator has determined that the previous certification or recertification requirements in the State do not conform to the requirements of subsection (e), the applicator must be recetified within two years after the date that the training programs of the State comply with the minium standatrds of the Administrator, or within an earlier time as the State could prescribe. The requirements of subsection (e) for supervised private applicators take effect one year after the expiration of the compliance period prescribed by subsection (h).

Subsection (j): The requirements of new subsection (j) regarding enforcement office training take effect one year after the Administrator issues the training materials specified in new subsection (g).

TITLE V—ADMINISTRATIVE REVIEW

Section 501—Cancellation after five years

Section 501 amends section 6(a) of the Act by striking out section 6(a)(2). The paragraph to be struck, which requires registrants to submit to the Administrator additional factual information regarding unreasonable adverse effects of a pesticide, would be relocated in new subsection (g) of section 6 (to be added by section 506).

Section 502—Cancellation and change in classification or labels

Section 502 amends subsection (b) of section 6 of the Act, which contains procedures for cancellation and change in classification. Under current law, section 6 contains no specific provisions relating to label changes.

Paragraph (1) of new subsection (b) restates existing law that if it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the Act or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of intent (1) to cancel its registration or to change its classification together with the reasons (including the factual bases) for the action of the Administrator; or (2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed. The notice of the intent of the Administrator must be sent to each reg-

istrant of the pesticide and be made public. In determining whether to issue the notice, the Administrator must include among those factors to be taken into account the impact of the proposed action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural commodities.

Not later than 60 days before sending the notice to a registrant or its being made public, whichever occurs first, the Administrator must provide the Secretary of Agriculture with a copy of the proposed notice and an analysis of the impact of the proposed action on the agricultural economy. The Secretary of Agriculture must provide comments on the notice and analysis to the Administrator within 30 days after receipt. If the Secretary of Agriculture provides comments in writing within 30 days, the administrator must publish in the Federal Register (with the notice) the comments of the Secretary and the response by the Administrator. If the Secretary of Agriculture does not provide comments in writing within 30 days, the Administrator may notify the registrant and make public the notice at any time after the 30-day period. The time requirements may be waived or modified to the extent agreed upon by the Administrator and the Secretary of Agriculture.

If the Administrator finds that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, the Administrator may waive the requirement of notice to the Secretary of Agriculture and submission to the Scientific Advisory Panel and proceed in accordance with the suspension provisions of subsection (c) of section 6.

Paragraph (2) of new subsection (b) restates and adds to existing law to provide that the action proposed in the notice of intent will become final and effective at the end of 30 days after receipt by the registrant or publication, whichever occurs later, unless within that time the registrant makes the necessary corrections, if possible, or a request for a hearing is made by a person adversely affected by the notice.

New requirements would be imposed if a request for a hearing is made. Specifically, the request must identify with the findings and conclusions of the decision of the Administrator that are disputed, and include a complete statement of the reasons and factual basis that support the request for a hearing. Any party to the proceeding may identify findings and conclusions in dispute.

As under existing law, if a hearing is held pursuant to such a request or pursuant to the determination of the Administrator to hold a hearing under paragraph (1)(A)(ii), a decision pertaining to registration or classification issued after completion of the hearing must be final.

Under a new provision, the Administrator also must convene a hearing on the request of a person without an economic interest in the pesticide, if the Administrator determines that the request persents a substantial issue of fact pertaining to whether the pesticide poses an unreasonable risk to man or the environment.

Paragraph (3) of new subsection (b) restates existing law that in taking any action to issue a notice of intent to cancel a registration, change its classification, or hold a hearing to determine whether or not the registration should be canceled or its classification changed, the Administrator must consider (1) restricting uses

of the pesticide as an alternative to cancellation and fully explain the reasons for the restriction; and (2) the impact of the action on production and prices of agricultural economy, and publish in the Federal Register an analysis of the impact.

Paragraph (4) of new subsection (b) contains new provisions for pesticide label changes that may be required by the Administrator through informal rulemaking.

Under paragraph (4), if the Administrator proposes a label change, the Administrator may notify the registrant of the proposed label change and provide for comments by the registrant during a 30-day period beginning on the date of the registrant's receipt of the notice. If the registrant notifies the Administrator that the registrant does not object to the proposed label change, then the change takes effect as prescribed by the Administrator. If the registrant does not submit comments to the Administrator in the 30-day period, the Administrator must notify the registrant that, if the registrant does not submit comments within 30 days after the second notice, the registration will be canceled without further notice.

If the label change proposed by the Administrator alters the areas or methods of permissible application, crops on which the pesticide may be used, or other use of the pesticide, or if a registant has objected to a label change proposed by the Administrator, the Administrator may require changes to the label of a pesticide by informal rulemaking under this paragraph. The Administrator may not make such changes by informal rulemaking if the Administrator finds the changes are equivalent to a cancellation of a use, render the pesticide unmarketable, or otherwise have a major economic impact on persons affected by such changes. The Administrator must provide notice in the Federal Register and not less than 45 days of comment; such notice must include a full description of the proposed label changes and a statement of the economic impact of the proposed label change on users of the pesticide and the public at large.

Paragraph (4) also provides that, if a regulation is promulgated that requires a label change, the Administrator must notify each registrant of the peticide subject to the regulation and provide a 30-day period for each registrant to apply for an amendment to the registration to comply with the regulation. If a registrant does not apply for an amendment within the 30-day period, the Administrator must issue a notice of intent to cancel the registration in accordance with paragraph (2). Such notice of intent to cancel will be deemed to have been issued under paragraph (1), described above, for purposes of the paragraph (2) hearing procedures.

A registrant or user of a pesticide subject to the regulation may request a hearing on the regulation in accordance with paragraph (2). The scope of the hearing is limited to (1) whether the pesticide complies with the regulation; (2) whether the regulation by its terms is applicable to the pesticide; and (3) whether, because of significant information that was not (and could not reasonably have been) presented in the rulemaking proceeding, it is unreasonable to require the pesticide to comply with the regulation.

Paragraph (4) requires a court, in an action for review of the regulation under section 16(e) of the Act, on request, to postpone the

effective date of the regulation until completion of the review action if the petitioner shows a likelihood of success on the merits in the action, and that implementation of the regulation before completion of action would cause a risk of substantial harm to the petitioner. However, the court may not postpone the effective date of the regulation if the Administrator shows that failure to implement the regulation would cause a risk of substantial harm to the public health or the environment.

User participation under section 502 applies only to actions initiated by the Agency.

Section 503—Public hearings and scientific review

Section 503 amends section 6(d) of the Act, which contains procedures for the conduct of hearings initiated under section 6(b) of the Act, to delete provisions relating to referrals of questions of scientific fact to a committee of the National Academy of Sciences.

Section 503 also amends section 6(d) of the Act to provide that, as soon as practicable after completion of a hearing on the cancellation of a pesticide registration, but not later than 18 months after the issuance of the cancellation notice that gave rise to the hearing, the Administrator must evaluate the data and reports and (1) issue an order revoking the section 6(b) notice of intent, or (2) issue an order either cancelling the registration, changing the classification, denying the registration, or requiring modification of the labeling or packaging of the article. (Under current law the Administrator has 90 days after completion of the hearing to so act.) This time period may be extended by the Administrator under extraordinary circumstances for not more than one year.

Section 504—Conditional registration

Section 504 strikes out language in section 6(e)(1) of the Act that provides authority for the Administrator to allow the continued use, distribution, or sale of existing stocks of a pesticide whose registration is canceled. This provision is combined in new subsection (g) of section 6 (to be added by section 506).

Section 505—Hearing procedures after public interim administrative review.

Section 505 amends section 6 of the Act (administrative review and cancellation) by redesignating subsection (f) as subsection (j) and adding a new subsection (f) to provide special procedures for a public hearing resulting from a public interim administrative review.

Paragraph (1) of subsection (f) provides that the special rules described below would govern hearings that result from the final decision of the Administrator in a public interim administrative review that (1) is initiated after 1 year after the date of enactment, (2) includes an opportunity for comment on a notice of preliminary determination, and (3) for which the time between the first public notice for the review and the close of the last comment period for the review is not less than 180 days. Otherwise, the provisions of subsection (d) of section 6 (as revised by section 503 of the bill) govern such hearings.

Paragraph (2) of new subsection (f) provides that any person who is adversely affected by a decision of the Administrator respecting a pesticide (including a person without an economic interest in the pesticide) following a special review may request, or intervene in, a hearing (in the manner provided by subsection (b)(2)(B) of section 6, as added by section 502 of the bill) within 30 days of the decision. A person may request a hearing, or intervene in a hearing, only if that person submitted comments during the special review proceeding and otherwise complied with the procedural provision of section 3(c)(8) governing special reviews (as added by section 212 of the bill).

By giving a person without an economic interest the right to a hearing under section 6, the Committee does not intend to limit such a person solely to this administrative procedure.

If the EPA rejects a petition to change a final decision not to cancel, suspend or otherwise restrict the use of a pesticide, any person has a right, under the same procedures and principles as in current law, to seek judicial review under section 16(a).

Paragraph (3) of new subsection (f) provides for certain procedures to be followed at a hearing following a special review. Under these provisions, at the request of a party to the hearing, the administrative law judge (ALJ) conducting the hearing may receive into evidence portions of the review record and other evidence that the party demonstrates are relevant and material to the disputed issues and are not unduly repetitious, if a competent witness is made available to be cross-examined on all matters relating to the evidence. Direct testimony of witnesses concerning scientific data or studies that were not, but could have been, obtained and submitted during the review by the exercise of due diligence are not admissible at the hearing. The right of parties to confront and cross-examine witnesses must be preserved on material issues of adjudicative fact, so long as the cross-examination is not unduly repetitious.

Paragraph (3) also provides that prehearing matters must be completed and the hearing begun not later than 120 days after the ALJ is appointed. The ALJ may establish a schedule for prehearing matters, including prehearing discovery and motions, and would ensure that the hearing schedule is met. The ALJ must issue appropriate orders for the purpose of simplifying and clarifying issues, specifying the order of presentation of witnesses, and allocating the time for cross-examination, briefing, and decision. Further discovery must be permitted after such 120-day period only on a determination by the administrative law judge that (1) the discovery would not in any way unreasonably delay the proceeding, (2) the information to be obtained is not otherwise obtainable, and (3) the information has significant probative value and is necessary to obtain relevant evidence needed to resolve a material issue in dispute.

Paragraph (3) states that any challenge to the authority to issue, or the procedural correctness of the issuance of, any notice of intent to cancel or change classification stemming from the review, or to any request for a hearing or motion to intervene, must be filed with the ALJ before the evidentiary phase of the hearing. Not later than 30 days before the hearing begins, the parties must ex-

change witness lists, a summary of testimony, and a list of all documents and exhibits expected to be introduced at the hearing. Thereafter, witnesses, documents, or exhibits may be added and narrative summaries of expected testimony amended by motion.

If new studies become available that were not available during the special review, the ALJ, on request of any party and if necessary, may submit the studies to the Scientific Advisory Panel for supplemental comment on an expedited basis (and under time limits set by the ALJ).

The ALJ must schedule the presentation and examination of witnesses so that the presentation of evidence is completed within 60 days after commencement of the hearing, except that this schedule is not to prejudice the right of a party to present evidence. The person who requested a hearing on an issue has the burden of going foward to present an affirmative case and has the burden of proof on that issue.

Under paragraph (3), a hearing must be completed and the Administrator must make a final decision within 300 days of the issuance of the determination (under the special review procedure) that gave rise to the hearing. The overall time limit may not be extended, except in exceptional circumstances in which it is essential for a fair and accurate determination of privotal facts central to the proceeding, and in no event by more than an additional 180 days. Other time limits under paragraph (3) may be extended for good cause. Failure to complete a hearing and make a final decision within 300 days are grounds for a civil action in a district court of the United States to seek an order to establish a schedule requiring the prompt completion of the hearing, but are not grounds for termination of the hearing or for making a final decision respecting the pesticide.

Section 506—Administrative review

Section 506 amends section 6 of the act to provide certain general provisions in a new subsection (g). Under new subsection (g)(1), a registrant, at any time, may request that any of its registrations be canceled or amended to delete one or more uses. Before acting upon the request, the Administrator must publish in the Federal Register a notice of the receipt of the request. Thereafter, the Administrator may approve the request.

Under new subsection (g)(2), a notice of denial of registration, intent to cancel, suspension, or intent to suspend issued under this Act, a notice issued under subsection (d)(4) or (e)(5)(A) of section 3A, or a notice issued under the third sentence of subsection (b)(4)(A), must be published in the Federal Register and be sent by certified mail, return receipt requested, to the registrant's or applicant's address of record on file with the Administrator. If the mailed notice is returned to the Administrator as undeliverable at that address, if delivery is refused, or if the Administrator otherwise is unable to accomplish delivery of the notice to the registrant or applicant after making reasonable efforts to do so, the notice would be deemed to have been received by the registrant or applicant on the date the notice was published in the Federal Register.

Under new subsection (g)(3), the Administrator may permit the continued use, distribution, or sale, or any combination thereof, of

existing stocks of a pesticide whose registration is canceled under the Act to such extent, under such conditions, during such periods, and for such uses as the Administrator may specify if the Administrator determines that such distribution, sale, or use is not inconsistent with the purposes of the Act and will not cause unreasonable adverse effects on the environment.

New subsection (g)(4) provides that if at any time after the registration of a pesticide the registrant has additional information regarding unreasonable adverse effects on the environment of the pesticide, the registrant must submit such information to the Administrator. For purposes of this paragraph, the term 'information' includes factual information and expert opinion regarding risks or benefits.

Section 507—Cancellation of registration based on false or invalid data

Section 507 amends section 6 of the Act by adding a new subsection (h). Paragraph (1) of new subsection (h) requires the Administrator to issue immediately an order of suspension and a notice of intent to cancel the registration of a pesticide if, prior to the effective date of the bill, the Administrator has previously determined in the Industrial Biotest validation process that data submitted by a registrant in support of the registration were invalid and (1) have not been replaced or (2) are in the process of being replaced on the date of enactment of the bill, but were not submitted by April 1, 1988; and (3) are material to the registration. The term "Industrial Biotest validation process" refers to a United States-Canada cooperative effort, begun in the late 1970s, to review studies by the Industrial Biotest Laboratories, Inc., to determine their scientific validity.

Paragraph (2) of new subsection (h) further specifies that, if after the effective date of the bill, the Administrator determines that invalid data are submitted or cited by a registrant in support of a registration, the Administrator may (1) require the registrant to submit valid replacement studies or data on an expedited schedule and to submit interim progress reports, or (2) issue a notice of intent to cancel the registration if the Administrator determines that it is in the public interest, taking into account the scope of the invalid data and the need to use the data to determine whether the pesticide may cause unreasonable adverse effects on the environment.

Under paragraph (3) of new subsection (h), if a registrant willfully submits material data known to be false in support of the registration of a pesticide, the Administrator must immediately issue notices of intent to suspend and cancel the registration.

Paragraph (4) new subsection (h) establishes procedures for hearing on the cancellation or suspension of a registration based on false or invalid data. Any suspension or cancellation under subsection (h) becomes final and effective 30 days after receipt by the registrant of a notice issued thereunder unless, during the 30-day period, a request for a hearing is made by a person adversely affected. The hearing must be conducted in accordance with section 6(c) suspension or 6(d) cancellation hearing procedures, as appropriate.

Section 508—Notice for stored pesticides with canceled or suspended registrations

Section 508 amends section 6 of the Act by adding a new subsection (i). Paragraph (1) of new subsection (i) requires any producer or exporter of a pesticide, pesticide registrant, applicant for or holder of an experimental use permit, pesticide testing facility, commercial applicator, or any person who distributes or sells any pesticide who has in his possession any pesticide that has had its registration canceled or suspended under this section to notify the Administrator and appropriate State and local officials of (1) such possession, (2) the quantity of such pesticide in his possession, and (3) the place at which such pesticide is stored.

Paragraph (2) of new subsection (i) requires the Administrator to transmit a copy of each such notice to the EPA regional office that has jurisdiction over the place of pesticide storage identified in the notice.

TITLE VI—REGISTRATION OF ESTABLISHMENTS

Section 601—Confidential information

Section 601 amends section 7(d) of the Act to provide that information about pesticide production locations submitted to the Administrator is not to be considered confidential or subject to the trade secrets provisions of the Act.

Section 602—Fact sheets and reports

Section 602 amends section 7 of the Act by adding a new subsection (e) to require any producer operating a pesticide production establishment to prepare or obtain a fact sheet for each active ingredient manufactured or used at the establishment. The producer must maintain copies of the fact sheet at the establishment and furnish a copy of the fact sheet to any person on request.

Each fact sheet must contain the chemical name, each common name, and any trade name of the active ingredient and a summary of relevant health, safety, and environmental data concerning the ingredient. Fact sheets must be revised as often as is necessary to reflect current information about the active ingredient. The Administrator may require a fact sheet to be amended to provide accurate and clear information to the public.

Each producer must furnish to the Administrator an annual report that includes the name of each ingredient for which a fact sheet is required that is manufactured or used by the producer, the location of the establishment, and a copy of the most current fact sheet. Fact sheets and annual reports must be made available to the public on request.

Nothing in section 602 is intended to affect authority or requirements under any other law, including the Comprehensive Environmental Response Compensation and Liability Act.

Section 603—Information requested

Section 603 amends section 7 of the Act to add a new subsection (f) to require the Administrator, consistent with section 3507(a)(1) of title 44 of the United States Code (public information collection

activities), to catalog and retrieve data in a manner to eliminate or reduce burdensome requests to registrants for submission of information, particularly those requests that require the submission of duplicate confidential data.

TITLE VII—BOOKS AND RECORDS

Section 701—Records

Section 701 amends section 8 of the Act to revise subsection (a) and delete subsection (b). Existing subsection (b) is amended and reincorporated into section 9 of the Act by section 801 of the bill.

Section 8, as rewritten, retains the substance of current subsection (a) and adds related new provisions. Under new subsection (a) of section 8, the Administrator may require, by regulation, any pesticide producer, exporter, registrant, applicant for registration, applicant for or holder of an experimental use permit, pesticide testing facility (a new term defined under section 106 of the bill), or commercial applicator, or any person who distributes or sells any pesticide, to (1) prepare, and maintain for reasonable periods of time, records that the Administrator finds necessary for the effective implementation or enforcement of the Act; (2) furnish to the Administrator reports stating the location where the records are maintained; and (3) furnish copies of the records to the Administrator on written request. Except as provided in new subsections (c), (d), and (e) of section 8 (to be added by section 702 of the bill) relating to applicator certification and training, the Administrator may not require any person who distributes or sells at retail a non-restricted use pesticide to prepare, maintain, or furnish any records for that pesticide under new subsection (a).

Under new subsection (b), the Administrator may not require any person to maintain records of: (1) financial data (except as required under section 19 of the Act), sales data, or pricing data; (2) personnel data, except for data concerning exposure of employees to pesticides or ingredients of pesticides, or concerning health effects on employees that could reasonably be attributable to the exposure; or (3) research or test data (other than data relating to registered pesticides, data relating to any pesticide for which an application for registration or for an experimental use permit has been filed, or data relating to testing at a pesticide testing facility).

Section 702—Records of pesticide applicators and dealers

Section 702 amends section 8 of the Act to add new subsections (c) through (g).

New subsection (c) provides rules regarding applicator records. It provides that the Administrator must require each commercial applicator to maintain records of pesticide applications, including the identity and amount of the pesticides applied and the date and location of the applications, for a period of two years after each application. No regulations prescribed by the Administrator under the Act may require any private applicator to maintain any records or file any reports or other documents, except as necessary to meet the provisions of section 2501 of the bill.

New subsection (d) deals with pesticide dealer records. It provides that the Administrator, by regulation, must require each pesticide

dealer to maintain a record of each sale or distribution of (1) a pesticide classified for restricted use and (2) any other pesticide designated by the Administrator by regulation because it may cause significant adverse effects on health or the environment. The records must include the identity of the pesticide sold or distributed, the identity of the person to whom the pesticide was distributed or sold, the date of the distribution or sale, and the amount of the pesticide distributed or sold. A pesticide dealer must maintain the records for three years after the date of the distribution or sale.

New subsection (e) deals with access to records and enforcement findings. It provides that any pesticide dealer or commercial applicator must afford, to an employee or former employee of the dealer or applicator, access to records required to be kept under new subsections (c) and (d) that directly relate to the employee's employment duties. Each pesticide dealer or commercial applicator must afford to a customer of the dealer or applicator access to the records that directly relate to any pesticide that the customer purchased from the dealer or that relate to any pesticide application made by the applicator at the request of the customer or under contract with a customer.

Each State enforcement agency, as part of an investigation or enforcement action in response to a formal complaint, must make available reports of the findings of the investigation of action to the complainant.

New subsection (g) defines the term "pesticide dealer" as used in section 8. Under new subsection (g) of section 8, the term means any person who, in the ordinary course of business, distributes or sells any pesticide that is classified for restricted use or is designated by the Administrator, by regulation under new subsection (d) of section 8 as a pesticide that may cause significant adverse effects on health or the environment.

TITLE VIII—INSPECTION OF ESTABLISHMENTS

Section 801—Authority to enter, inspect, and copy

Section 801 amends subsection (a) of section 9 of the Act, which currently provides general authority for the Administrator, in enforcing the Act, to enter premises and inspect and obtain samples of pesticides. New subsection (a) retains the substance of the first sentence of the current subsection, adds provisions (currently in section 8) relating to copying of records, and adds a related new provision. The last five sentences of current subsection (a) are deleted, but the matters they cover are included in new subsection (d) of section 9, to be added by section 803.

Under new subsection (a), officers or employees of the United States or of any State, duly designated by the Administrator are authorized, at reasonable times, to (1) enter any place where any pesticide, active ingredient, or device is distributed or sold to inspect and obtain samples of any pesticide, active ingredient, or device being distributed or sold at the place or of any packaging or labeling of the pesticide, active ingredient, or device; (2) enter any place where there are located any records required by the Act, including any place reported under new subsection (a) of section 8 as a location where records are maintained, to inspect and obtain

copies of the records; (3) enter any pesticide testing facility (a new term defined under section 106 of the bill) to inspect the facility and the testing being conducted at the facility and inspect and obtain copies of any records required by the Act to be maintained by the pesticide testing facility; and (4) enter any place where the officer or employee has reason to believe that the Act has been or is being violated by any person other than a private applicator, to inspect the place and obtain evidence of the violation.

Section 802—Warrants

Section 802 amends subsection (b) of section 9 of the Act, which deals with entry, inspection, and seizure warrants. Under new subsection (b), authority is provided for officers or employees of the United States or of any State, duly designated by the Administrator, to obtain and to execute warrants authorizing (1) entry, inspection, and obtaining of evidence for the purposes of section 9, as revised by the bill; (2) inspection and copying of all records required under the Act; and (3) seizure of any pesticide or device that is in violation of the Act. New subsection (b) retains the substance of current subsection (b), as implemented by the Environmental Protection Agency.

Section 803—Procedure, coordination, and criminal violations

Section 803 amends section 9 of the Act by adding a new subsection (d) relating to the procedures to be followed before entry or inspection of premises is made. The provisions of new subsection (d) are similar to those of the last three sentences of current section 8(b) (to be deleted under section 701) and the last five sentences of current section 9(a) (to be deleted under section 801).

PROTECTION OF TRADE SECRETS AND OTHER INFORMATION

Section 901—Disclosure of inert ingredients

Section 901 amends section 10(d) of the Act to allow the disclosure of information on inert ingredients in ingredient statements.

Section 902—Data disclosure to States

Section 902 amends section 10 of the Act by adding a new subsection (h) to allow the Administrator to disclose to a State any data or information acquired under the Act if the State assures the Administrator, and the Administrator determines, that the submitter of the data or information will receive no less protection with respect to the disclosure and use of the data or information by the State than is provided under the Act (see paragraph (1) of new subsection (h).

New subsection (h), in paragraph (3), requires the Administrator to disclose such data or information to any State based on such assurance if the State makes further assurance, and the Secretary determines, that the law of the State allows the submitter to recover just compensation in a civil action against the State for losses that result from the disclosure or use of the data or information by the State or its employees or agents in a manner inconsistent with section 3 or 10 of the Act.

Paragraph (2) of new subsection (h) provides that, for purposes of any action that may lie against the United States for just compensation under section 1491 of title 28, United States Code, the disclosure or use by a State of data or information, provided by the Administrator under paragraph (1), in a manner inconsistent with section 3 or 10 of the Act must be considered a taking of property and the act of the State shall be considered an act of the United States.

TITLE X—STANDARDS

SECTION 1001—STANDARDS APPLICABLE TO PESTICIDE APPLICATORS

Section 1001 repeals section 11 of the Act (standards applicable to pesticide applicators) to conform with the amendments made to section 8 of the Act by section 702.

TITLE XI—UNLAWFUL ACTS

SECTION 1101—UNLAWFUL ACTS

Section 1101 amends paragraph (1)(A) of subsection (a) of section 12 of the Act, which describes the acts that are prohibited under the Act. Paragraph (1)(A) of subsection (a) (which currently provides that it is unlawful to distribute or sell pesticides that are not registered except as provided in section 6(a)(1) of the Act (disposal of existing stocks)) is technically rewritten to provide that it is unlawful to distribute or sell any pesticide that is not registered under section 3 of the Act or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under the Act.

Similarly, section 1101 technically revises paragraph (2)(B) of subsection (a) to conform to the changes to be made in sections 8 and 9 of the Act by titles VII and VIII of the bill. Under paragraph (2)(B), as rewritten it is unlawful for any person to refuse to prepare, maintain, or submit any records required by or under the Act; submit any reports required by or under the Act; or allow any entry, inspection, copying of records, or sampling authorized by the Act.

Section 1101 further amends section 12(a)(2) to—

(1) add to the current prohibition under subparagraph (F)—against the use of a restricted use pesticide for purposes not in accord with the Act and its regulations—a prohibition against the distribution or sale (as the term is defined under new subsection (rr) of section (2)) for such purposes.

(2) revise the prohibition in subparagraph (J) against violations of suspension orders under section 6 to add references to suspension orders under sections 3(c)(2)(B) and new 3A (to be added to the Act by section 301 of the bill); and

(3) revise subparagraph (K) (which currently prohibits violations of "any cancellation of registration of a pesticide under section 6, except as provided by section 6(a)(1)") so that it would prohibit violations of "any cancellation order issued under this Act"; and

(4) with respect to the prohibition against falsification of records under paragraph (2)(M), change a reference to records

maintained "under section 8" to records maintained "under this Act".

Section 1101 further amends paragraph (2)(P) of section 12(a) of the Act to make it a violation of the Act to obtain and use records acquired under new subsection (e) of section 8 (to be added by section 702 of the bill) in furtherance of a commercial purpose.

Section 1101 also adds new subparagraphs (R), (S), (T) and (U) to paragraph (2) of subsection (a) to add three new prohibitions as follows:

(1) to falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed, and submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by the Act.

(2) to submit to the Administrator data known to be false in support of a registration.

(3) to violate any regulation issued under section 3(a), 19, 25(c)(3), or 25(f) of the Act. (Section 3(a), as amended by sections 201 and 202 of the bill, authorizes the Administrator to regulate the sale, distribution, and use of unregistered pesticides. Section 19 authorizes the Administrator to establish procedures for the recall storage, disposal, and transportation of pesticides. Section 25(c)(3) authorizes the Administrator to establish pesticide packaging standards. Section 25(f), to be added by section 2003, provides for a worker health and safety program.)

(4) to violate an order issued under section 31(f)(2) (which provides for a site-specific response to pesticide contamination of a drinking water well).

Section 1101(b) amends section 12 of the Act by adding a new subsection (c), formerly set forth in section 14(b)(4) of the Act, providing that when construing and enforcing the provisions of the Act, the act, omission, or failure of any officer, employee, agent, or other person acting for or employed by any person is be deemed to be the act, omission, or failure of the employer as well as that of the person employed.

TITLE XII—PENALTIES

Section 1201—Penalties and subpoenas

Section 1201(a) amends subsection (a) of section 14 of the Act, which provides civil penalties for violations of the Act. The amendment revises paragraphs (1) and (2) of subsection (a) to increase penalties and provide penalties for subsequent violations, and conforms subsection (a) to other changes to the Act to be made by the bill.

As revised, paragraphs (1) and (2) provide that—

(1) any person who is (or is employed by or acting for) a registrant, applicant for a registration, or pesticide testing facility, or a holder of a pesticide that is subject to a regulation under section 19(b), that violates any provision of the Act may be assessed a civil penalty by the Administrator of not more than

$25,000 for each offense. If such person violates a provision of the Act after having violated the same or similar provision of the Act, the Administrator may assess a civil penalty of not more than $50,000 for each subsequent violation (new paragraph (1)(A));

(2) any commercial applicator of restricted use pesticides, or any other person not described by the preceding paragraph who distributes or sells a pesticide or device that violates any provision of the Act may be assessed a civil penalty by the Administrator of not more than $10,000 for each offense. If the person violates a provision of the Act after having violated the same or similar provision of the Act, the Administrator may assess a civil penalty of not more than $20,000 for the subsequent violation (new paragraph (1)(B)); and

(3) any private applicator who violates any provision of the Act subsequent to receiving written warning from the Administrator or following a citation for a prior violation and any other person not described in item (1) or (2) above that violates any provision of the Act my be assessed a civil penalty by the Administrator of not more than $1,000 for each offense. If the person violates a provision of the Act after having violated the same or similar provision of the Act, the Administrator may assess a civil penalty of not more than $2,000 for the subsequent violation (new paragraph (2)).

Section 1201(a) also adds a new provision to paragraph (2) to authorize the Administrator to waive the requirement for a warning or citation for a first offense by a private applicator if the Administrator determines that the violation was intentional or caused or had potential to cause significant harm to health or the environment (Note: A provision currently in paragraph (2) specifically applicable to pest control operations is deleted by section 1201).

Section 1201(a) amends paragraph (3) of section 14(a), regarding hearings to assess civil penalties, to provide that if a person neither resides nor has his principal place of business in the United States, the Administrator may designate a site for the hearing in the United States that is reasonably convenient for the parties.

Section 1201(a) also amends paragraph (4) of sectioon 14(a) to require the Administrator, in determining the amount of a civil penalty, to consider the economic benefit (if any) gained by the violation of the Act.

Section 1201(b) amends section 14(a) by adding a new paragraph (6) to authorize the Administrator, in connection with administrative proceedings under the civil penalties provisions of the Act, to issue subpoenas compelling the attendance and testimony of witnesses and subpoenas duces tecum and to request the Attorney General to bring an action to enforce a subpoena. The district courts of the United States have jurisdiction to enforce the subpoenas and impose sanctions.

Section 1201(c) amends paragraph (1) of section 14(b) of the Act, which provides criminal penalties for violations of the Act by persons (except private applicators) in the pesticide industry. The amendment increases some penalties and conforms paragraph (1) to other changes in the Act made by the bill.

As revised, paragraph (1) provides that any person who is (or is acting for or employed by) a registrant, producer, or pesticide testing facility, or a holder of a pesticide that is subject to a regulation under section 19(b), that knowingly violates any provision of the Act shall be fined not more than $50,000 or imprisoned for not more than 2 years, or both (new paragraph (1)(A)). Any commerical applicator of a restricted use pesticide, or any other person not described by paragraph (1)(A) who distributes or sells pesticides or devices that knowingly violates any provision of the Act shall be fined not more than $25,000 or imprisoned for not more than 2 years, or both (new paragraph (1)(B)).

Section 1201 also amends paragraph (2) of section 14(b) of the Act to increase the maximum penalty for the knowing violation of the Act by a private applicator or other person not covered by pargraph (1) from $1,000 to $2,000, and increase the possible term of imprisonment from 30 days to 60 days.

Section 1201 (d) amends paragraph (3) of section 14(b) of the Act to provide that any person who, with intent to defraud, uses or reveals information relative to the formula of a product acquired under section 3 of the Act (which includes the new preregistration access to data provision added by section 214 of the bill) shall be fined not more than $25,000, or imprisoned for not more than 3 years, or both. Current law provides a fine of not more than $10,000 and the same maximum prison term.

Section 1201 (d) also adds a new provision to paragraph 3 of section 14(b) of the Act providing that any person (including any officer, contractor, or employee of the United States or a State) who is granted preregistration access to data and, in furtherance of a commerical purpose involving the production, registration, distribution, or sale of a pesticide, knowingly violates the preregistration access to data provisions of section 214, or knowingly allows data to be made available in violation of those provisions shall be fined not more than $100,000, or imprisoned for not more than 3 years, or both.

Section 1201 (e) repeals paragraph (4) of section 14(b) to reflect the placement of the provisions in new subsection (d) of section 12.

TITLE XIII—INDEMNITIES

Section 1301—Indemnities

Section 1301(a) amends section 15 of the Act, effective 180 days after the date of enactment of the bill, to limit eligiblity for indemnity payments for stocks of suspended and canceled pesticides.

Similar to current law, paragraph (1) of new subsection (a) provides that, subject to other provisions of section 15 (including, specifically, subsection (a)(4)), if (1) the Administrator notifies a registrant under section 6(c)(1) that the Administrator intends to suspend a registration or that an emergency order of suspension of a registration under section 6(c)(3) has been issued, (2) the registration in question is suspended under section 6(c), and thereafter is canceled under section 6(b), 6(d), or 6(g), and (3) any person who owned any quantity of the pesticide immediately before the notice of intent to suspend suffered losses by reason of suspension or can-

cellation of the registration, the Administrator must make an indemnity payment to the person.

Under paragraph (2), the Administrator may not make an indemnity payment if the Administrator determines that the person had knowledge of facts that, in themselves, would have shown that the pesticide did not met the requirements of section 3(c)(5) (approval of registration) of the Act and continued thereafter to produce the pesticide without giving timely notice of such facts to the Administrator. A similar prohibition is contained in current section 15.

Paragraph (3) of new subsection (a) contains a new reporting requirement. If the Administrator takes an action under paragraph (1) that requires the payment of indemnification, the Administrator must report to the Committee on Agriculture of the House of Representatives, the Committee on Agriculture, Nutrition, and Forestry of the Senate, and the Committees on Appropriations of the House of Representatives and the Senate on the action taken that requires the payment of indemnification, the reasons for taking the action, the estimated costs of the payment, and a request for the appropriation.

Paragraph (4) adds a new prohibition that the Administrator may not make a payment of indemnification under paragraph (1) unless a specific line item appropriation of funds has been made in advance for the payment. No obligation by the Federal Government is incurred if an advance appropriation is not made.

New subsection (b) provides that if (1) the Administrator notifies a registrant under section 6(c)(1) that the Administrator intends to suspend a registration or that an emergency order of suspension of a registration under section 6(c)(3) has been issued, (2) the registration in question is suspended under section 6(c), and thereafter is canceled under section 6(b), 6(d), or 6(g), and (3) any person who owned any quantity of the pesticide for the purpose of applying or using the pesticide as an end user, rather than for purposes of distributing or selling it or further processing for distribution of sale, suffered losses by reason of suspension or cancellation of the registration, the person is entitled to an indemnity payment for such quantity of the pesticide from the appropriation provided under section 1304 of title 31, United States Code (the Judgment Fund of the United States Treasury). The Committee intends to authorize indemnification for a person who owned the pesticide only for the purpose of applying or using it, and does not intend to authorize indemnification for a person who owned the pesticide for the purpose of selling and applying it. Quantities of pesticides that are owned for purposes of distribution, sale, or further processing will not qualify for indemnification. The Committee intends to exclude persons who sell the service of applying pesticides from indemnification in under this subsection.

Paragraph (2)(A) of new subsection (b) provides that any registrant, wholesaler, dealer, or other distributor (hereinafter in this paragraph referred to as a "seller") of a registered pesticide who distributes or sells the pesticide directly to any person not described as an end user in paragraph (1)(C) must, with respect to any quantity of the pesticide that such person cannot use or resell as a result of the suspension or cancellation of the pesticide, reimburse such person for the cost of first acquiring the pesticide from

the seller (other than the cost of transportation, if any), unless the seller provided to the person at the time of distribution or sale a notice, in writing, that the pesticide is not subject to reimbursement by the seller.

Under paragraph (2)(B), dealers and distributors would be eligible for indemnity payments in limited circumstances. If—

(1) the Administrator notifies a registrant under section 6(c)(1) that the Administrator intends to suspend a registration or that an emergency order of suspension of a registration under section 6(c)(3) has been issued;

(2) the registration in question is suspended under section 6(c), and thereafter is canceled under section 6(b), 6(d), or 6(g);

(3) any person who, immediately before the notice to the registrant under clause (i)—

(a) had not been notified in writing by the seller, as provided under subparagraph (A), that any quantity of the pesticide owned by such person is not subject to reimbursement by the seller in the event of the cancellation or suspension of the pesticide; and

(b) owned any quantity of the pesticide for purposes of distributing or selling it or for purposes of further processing it for distribution or sale directly to an end user; suffered a loss by reason of the suspension or cancellation of the pesticide; and

(4) the Administrator determines on the basis of a claim of loss submitted to the Administrator by the person, that the seller did not provide the notice specified in subparagraph (A) to such person, and the seller is and well continue to be unable to provide reimbursement of such person, as provided under subparagraph (A), for the loss referred to in clause (iii), as a result of insolvency or bankruptcy of the seller and the seller's resulting inability to provide such reimbursement; the person is entitled to an indemnity payment under subsection (b) for such quantity of the pesticide.

Paragraph (2)(C) provides that if an indemnity payment is made by the United States under paragraph (2), the United States shall be subrogated to any right that would otherwise be held under paragraph (2) by a seller who is unable to make a reimbursement in accordance with such paragraph with regard to reimbursements that otherwise would have been made by the seller.

Paragraph (3) provides that any payment required to be made under paragraph (1) or (2) must be made from the appropriation provided under section 1304 of title 31, United States Code.

Paragraph (4) states that an administrative settlement of a claim for such indemnity may be made in accordance with the third paragraph of section 2414 of title 28, United States Code, and shall be regarded as if it were made under that section for purposes of section 1304 of title 31, United States Code.

New subsection (c) is similar to current subsection (b) of section 15. New subsection (c) provides that the amount of an indemnity payment under subsection (a) or (b) to any person must be determined on the basis of the cost of the pesticide owned by the person (other than the cost of transportation, if any) immediately before the issuance of the notice to the registrant referred to in subsection

(a)(1)(A), (b)(1)(A), or (b)(2)(B)(i), except that in no event may an indemnity payment to any person exceed the fair market value of the pesticide owned by the person immediately before the issuance of the notice. Notwithstanding any other provision of this Act, the Administrator may provide a reasonable time for use or other disposition disposal of the pesticide. In determining the quantity of any pesticide for which indemnity must be paid under this section, proper adjustment must be made for any pesticide used or otherwise disposed of by the owner.

Section 1301(b) provides that any obligation of the Administrator to pay an indemnity arising under section 15, as it existed prior to the effective date of the amendment made by section 1301, must be made from the appropriation provided under section 1304 of title 31, United States Code. An administrative settlement of a claim for such indemnity may be made in accordance with the third paragraph of section 2414 of title 28, United States Code, and must be regarded as if it were made under that section for purposes of section 1304 of title 31, United States Code.

The Committee wishes to confirm that these amendments to section 15 shall apply only prospectively to regulatory actions taken by the Administrator after the effective date of these amendments. These amendments shall not affect any obligation of the Administrator arising under section 15 that is still pending, either administratively or judicially, on the effective date.

TITLE XIV—ADMINISTRATIVE PROCEDURE

Section 1401—Review of regulations

Section 1401 amends section 16 of the Act (administrative procedure and judicial review) by adding a new subsection (e) to prescribe the procedures for the review of regulations issued under the Act.

Paragraph (1) of new subsection (e) provides that any regulation issued under the Act and first published in the Federal Register in final form after the effective date of the bill or any refusal of a petition to modify or rescind a regulation issued under the Act is reviewable only as provided in provided in subsection (e). Any person may obtain judicial review of the regulation or the refusal by filing a petition for review in the United States court of appeals for the circuit wherein the person resides or has its principal of business or in the United States Court of Appeals for the District of Columbia Circuit. Any such petition for review of a regulation must be filed within 120 days after the date of promulgation of the regulation as designated by the Administrator in the Federal Register. Any such petition for review of a refusal to modify or rescind a regulation must be filed within 120 days after the refusal. In either case, the scope of review must be as specified in section 706 of title 5, United States Code.

Section 706 of title 5 provides that "To the extent necessary to decision and when presented to the review shall decide all relevant questions of law, interpret constitutional and statutory provision, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitation, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trail de novo by the reviewing court."

In making the foregoing determinations, the court must review the whole record or those parts of it cited by a party, and due account must be taken of the rule of prejudicial error.

The commencement of proceedings under subsection (e) may not operate as a stay of the regulation, unless specifically ordered by the court to the contrary.

Paragraph (2) of new subsection (e) provides that a regulation issued by the Administrator or a refusal by the Administrator of a petition to modify or rescind a regulation issued under the act shall not be subject to judicial review in (1) any suspension, cancellation, or denial proceeding under the Act, or in any appeal therefrom, or (2) in proceedings or appeals under section 13 (stop sale, use, removal and seizure) or section 14(a) (civil penalties) of the act, or under subsection (c) of section 16 (district court actions to enforce and restrain violations of the Act), except on request of an agricultural producer adversely affected by the action.

Under paragraph (3) of new subsection (e), if a person who is a party to a proceeding described above that is based on a regulation issued under the Act petitions the Administrator to modify or rescind a regulation, the application of the regulation must be stayed until the Administrator issues a final decision on the petition.

Paragraph (4) of new subsection (e) defines the term "agricultural producer", as used in subsection (e), to mean a nongovernmental producer of agricultural commodities who (1) uses or supervises the use of any pesticide for the production of such commodities on property he or his employer owns or rents, or (2) without compensation other than the trading of personal services, assists another agricultural producer with the application of pesticides on the other person's land.

TITLE XV—IMPORTS AND EXPORTS

Section 1501—Pesticides and devices intended for export

Section 1501 amends subsection (a) of section 17 of the Act, which imposes requirements applicable to exported pesticides. Paragraph (1) of new subsection (a) provides that, notwithstanding any other provision of the Act, no pesticide, device, or active ingredient used in producing a pesticide intended solely for export to any foreign

country may be considered in violation of the Act when prepared or packed according to the specifications or directions of the foreign purchaser, except that any producer of a pesticide, device, or active ingredient used in producing pesticides is subject to provisions of the Act that—

(1) define label and labeling;

(2) provide that a pesticide is misbranded under certain conditions; and

(3) in new subsection (a), regulate pesticides and devices intended for export.

This provision is the same as existing law, except that exporting producers are also subject to the misbranding provisions of section 2(q)(1)(I) of the Act, added by section 103 of the bill.

Paragraph (2)(A) of new subsection (a) restricts the export of a pesticide, device, or active ingredient for which a cancellation, suspension, or restricted use classification has become effective, the registration of which has been voluntarily withdrawn by the registrant, or that is not registered for any use.

Under paragraph (2)(B), the pesticide, device, or active ingredient described above may not be exported unless prior to the intended date of the first shipment each calendar year the exporter has transmitted to the Administrator—

(1) the name of the pesticide and the common and chemical names of the active ingredient;

(2) the name and address of the exporter;

(3) the name and address of the foreign purchaser;

(4) the approximate dates and quantities of shipments of such pesticide, device, or active ingredient to such country during the following calendar year;

(5) the manner of transport of such shipments; and

(6) the ports of entry.

Paragraph (2)(C) provides that the report described above must contain a notarized certification that—

(1) the country of import is named in the list maintained by the Administrator pursuant to subparagraph (E) and that the pesticide, device, or active ingredient is approved for use in that country;

(2) the exporter will not permit such shipment to leave the United States until the Administrator has received written evidence that the notification required by subparagraph (D) was delivered to the appropriate government regulatory office in the country of import;

(3) the pesticide, device, or active ingredient is manufactured, processed, packaged, and held in conformity with standards for composition and quality of the country of import, the World Health Organization, and the Food and Agriculture Organization and is not adulterated or misbranded;

(4) the outside of the shipping package will be prominently labeled with the following statement: "This pesticide may be sold or offered for sale only in the following countries: ," the blank space being filled with a list of the countries to which export of the pesticide, device, or active ingredient is authorized under this paragraph;

(5) in the case of a pesticide, device, or active ingredient referred to in clause (ii), (iii), or (iv) of subparagraph (A), that the outside of the shipping package will be conspicuously labeled with the following statement: 'Not registered for use in the United States of America' in the official language of the country of import and appropriate local languages; and

(6) the exporter will notify the Administrator of any changes in the information supplied pursuant to this subparagraph or subparagraph (B) after a shipment has left the United States, including in particular any diversion of such shipment to countries not named in the original information supplied to the Administrator.

Paragraph (2)(D) of new subsection (a) provides that not later than 30 days after the receipt of the report required by the previous paragraph, the Administrator must notify the appropriate government regulatory office in the country of import. Such notification must contain the following information in the official language or languages of the country of import—

(1) the information required by clauses (i) through (vi) of subparagraph (B);

(2) a statement of the reasons why the pesticide, device, or active ingredient was canceled, suspended, voluntarily withdrawn, is not registered in the United States, or has been classified for restricted use, and the list of restrictions;

(3) name and address of the office of the Environmental Protection Agency that, on request by the importer or official of the importing country, can provide additional information on the pesticide, device, or active ingredient.

Such notification must request a written acknowledgment that the notification was delivered to the appropriate government regulatory office in the country of import. Within 30 days of receipt of the country of import's acknowledgment, the Administrator must forward such acknowledgment to the exporter.

Paragraph (2)(E) authorizes the Administrator to compile a list of countries to which a pesticide, device, or active ingredient may be exported under this paragraph. Before adding a country to the list, the Administrator must make a finding that each of the following criteria has been satisfied with respect to that country:

(1) the existence and effective operation of statutory or regulatory requirements that require the review of pesticides for human and environmental toxicity by an entity of the government of such country and that authorize the approval of only those pesticides that have been determined not to have unreasonable adverse effects on the environment or human health by experts independent of any pesticide manufacturer and employed by or acting on behalf of such entity, and qualified by scientific training and experience to evaluate the safety of pesticides;

(2) the existence and effective operation of statutory or regulatory requirements that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing pesticides in the country are adequate to preserve their identity, quality, purity, and strength;

(3) the existence of effective operation of statutory or regulatory requirements for withdrawing approval of and removing from the market, pesticides found not to be safe or effective;

(4) the existence and effective operation of statutory or regulatory requirements that the labeling of pesticides must be in accordance with the terms of approval of the pesticide;

(5) the existence and effective operation of statutory or regulatory requirements for the collecting and recording of acute and chronic health effects and environmental effects;

(6) the existence and effective operation of statutory or regulatory requirements for making health, safety, and environmental information available to workers and affected communities;

(7) the existence and effective operation of statutory or regulatory requirements assuring the availability to workers and affected communities of training, protection equipment, and emergency procedures; and

(8) the existence and effective operation of statutory or regulatory requirements to assure that pesticide advertising encourages proper use, notifies of pesticide hazards, and is not misleading.

Additions or amendments to the list must be made by regulation with a minimum 90-day period for public comment. The Administrator must give particular weight to comments from the public in the country concerned.

Paragraph (2)(G) provides that documents referred to in paragraph (2) must be made available to the public on request.

Paragraph (3) of new subsection (a) requires that the label of pesticides intended for export from the United States be written in the official language of the country of import and appropriate local languages. Labels of pesticides intended for export may not refer to compliance with the laws of the United States except for a statement (required under section 2(q)(1)(H) of the Act) that the pesticide is "Not Registered for Use in the United States", unless the label also contains or is accompanied by a description of the relevant requirements of the law.

Paragraph (4) of new subsection (a) provides that no information required to be disclosed pursuant to this section may be withheld from a foreign government on the basis of a claim of trade secrecy or confidential business information. Where such information has been claimed confidential by the submitter, it must be accompanied, when supplied to a foreign government, by a statement to that effect and a request to the foreign government to preserve its confidential character.

Section 1501 provides that section 17(a)(2) of the Act, as amended, shall become effective 90 days after the date of enactment of the bill.

Section 1501 requires the Administrator, not later than 90 days after the date of enactment of the bill, to publish in the Federal Register preliminary guidelines regarding—

(1) the form of the report and certification required under paragraphs (B) and (C) of section 17(a)(2);

(2) procedures under section 17(a)(2)(D) for forwarding to exporters acknowledgments of receipt of notifications by the ap-

propriate government regulatory office in the country of import;

(3) translation of labels required under section 17(a)(3) into foreign languages;

(4) retention of shipping documents and other pertinent records by exporters under section 17(a);

(5) list of appropriate regulatory agencies for purposes of import notification; and

(6) procedures for public access to documents submitted by exporters under such section.

Section 1502 further provides that the Administrator shall issue such regulations as are necessary to carry out paragraphs (2), (3), and (4) of subsection (a) and subsection (b) not later than 1 year after the date of enactment of the bill.

Section 1502—Cancellation notices furnished to foreign governments

Section 1502 amends subsection (b) of section 17 of the Act retaining the substance of current law and adding related provisions. New subsection (b) requires the Administrator promptly to transmit through the Secretary of State a notice, at such time the action is taken and annually thereafter, to the appropriate governmental regulatory offices of other countries and to appropriate international agencies whenever a registration, or a cancellation or suspension of the registration, of a pesticide becomes effective or ceases to be effective, or whenever a pesticide is classified for restricted use.

The contents of the notice must include the reasons for the regulatory action taken; for canceled or suspended registrations, information concerning other registered pesticides that could be used in lieu of the pesticide; and the name and address of the office of the Environmental Protection Agency that on request can provide additional information on the pesticide.

Section 1503—Cooperation in international efforts

Section 1503 amends subsection (d) of section 17 to restate current law and add new provisions. New paragraph (1) of subsection (d) requires the Administrator, in cooperation with the Department of State, other appropriate Federal agencies, and nongovernmental and international organizations, to actively participate in international efforts to develop improved pesticide research and regulatory programs and improved strategies for sustainable agriculture, including integrated pest management. Current law contains a simiilar requirement, but does not reference nongovernmental and international organizations.

New paragraph (2) of subsection (d) requires the Administrator to provide foreign countries with technical assistance to develop comprehensive pesticide regulatory programs.

Under new paragraph (3), the Administrator, within 1 year after the effective date of this subsection and every 3 years thereafter, must conduct and publich a survey of all countries that import pesticides from United States exporters or from which the United States imports agricultural commodities, to ascertain what procedures are in place in each country regarding registration, labeling, and training to ensure safe handling, transportation, application,

and disposal of pesticides; and to control residues on foods to meet tolerances established under United States law.

Paragraph (4) requires the Administrator to convene, within one year of the effective date of subsection (d), in cooperation with the Department of State, a meeting held in the United States under the auspices of the Organization for Economic Cooperation and Development, and to sponsor such other meetings as may be necessary, to actively encourage the members of the Organization to adopt a binding multilateral convention containing regulatory measures for exported pesticides at least as stringent as those in the Act.

Paragraph (5) requires the Administrator to report to Congress annually on the activities conducted under subsection (d) and the results thereof.

TITLE XVI—DISPOSAL AND TRANSPORTATION

Section 1601—Storage, disposal, transportation, and recall

Section 1601 amends section 19 of this Act (7 U.S.C. 136 q) by deleting all subsections and inserting the following subsections:

Paragraph (1) of subsection (a) provides authority to the Administrator to require that registrants provide data or information needed about safe storage and disposal of excess quantities of a pesticide, and labeling about requirements and procedures for the transport, storage and disposal of pesticides, pesticide containers, rinsates containing pesticides and other material. Registrants may be required to provide evidence of sufficient financial and other resources to carry out a recall and disposal of a suspended and canceled pesticide.

Paragraph (2) provides that the Administrator may issue requirements and procedures for the storage and disposal of suspended and canceled pesticides. Nothing in this paragraph is intended to affect existing authority under the Resource Conservation and Recovery Act of 1976 (42 U.S.C. 6901 et. seq.) to regulate suspended and canceled pesticides that are hazardous wastes.

Paragraph (1) of subsection (b) provides the Administrator with authority to order a recall of a pesticide.

Paragraph (2) establishes authority and procedures for the Administrator to authorize a voluntary recall of a pesticide by the registrant and others in the chain of distribution. The Administrator may disapprove a plan submitted by a registrant after an informal hearing if he determines that the plan is inadequate to protect the public health or the environment.

Paragraph (3) provides that the Administrator may order a recall by regulation to be conducted by current or former registrants, distributors, sellers or their successors in interest.

Paragraph (4) requires persons subject to a recall order to arrange for and provide notice of storage facilities, to accept and store stocks tendered by persons who obtained the pesticide directly or indirectly from such person, to provide for proper transportation of the pesticide to the storage facility, and to take reasonable steps to inform pesticide holders of the terms of the recall and means for tendering and transporting the pesticide to a storage facility.

Paragraph (5) requires that the recall plan indicate the level of the distribution chain to which the recall extends and the means to verify the plan's effectiveness.

Paragraph (6) limits any recall plan to the procedures outlined in this subsection.

Paragraph (1) of subsection (c) requires registrants who wish to be eligible for storage cost reimbursement as a result of a recall under subsection (b), to submit a plan as soon as practicable for storage and disposal to the Administrator that meets criteria established by the Administrator. The Committee considers six months to be a reasonable period of time. The Administrator must, by regulation, establish minimum criteria against which a registrant-submitted plan for storage and disposal of a pesticide whose registration has been suspended and canceled shall be judged. The Committee contemplates that such criteria shall be designed in such a manner as to (1) allow the Administrator to reject a plan that clearly does not provide a scheme for safe storage, and safe, practicable disposal of the pesticide in question that is reasonable in its general approach. The criteria are to be minimum standards for use in deciding whether a plan has been submitted in good faith and should be accepted for further consideration and possible modification, rather than standards for final approval of plan.

Paragraph (2) sets out the conditions for reimbursement to a registrant for storage costs incurred and paid by the registrant as a result of a recall of suspended and canceled pesticides. Reimbursement shall be paid as follows:

(A) none of the costs incurred prior to submission of a disposal plan that meets criteria established by the Administrator;

(B) 100 percent of costs incurred by the registrant after a disposal plan that meets Agency criteria is submitted to the Administrator or the date the pesticide registration is canceled, whichever is later;

(C) 50 percent of the costs incurred by the registrant for one year beginning the day the plan is approved or the date the pesticide registration is canceled, whichever is later;

(D) none of the costs incurred by the registrant for three years beginning on the 36th day after the plan is approved for the pesticide registration is canceled, whichever is later;

(E) 25 percent of the costs incurred by the registrant for beginning on the first day of the 5th year following the date that the plan is approved or the pesticide registration is canceled, whichever is later, and ending on the date that a disposal permit is obtained or an alternative plan for disposal has been developed. The reference is a permit includes State or EPA permits or modifications of such permits. An alternative plan for disposal would be developed as a result of consultation between the registrant and the Administrator.

Paragraph (1) of subsection (d) provides for voluntary agreements between sellers and buyers of pesticides or pesticide ingredients to allocate the costs or storage, transport or disposal of a pesticide.

Paragraph (2) provides for Congressional review of rules or regulations promulgated with respect to recall, storage, transport and disposal of a suspended and canceled pesticide.

Paragraph (3) limits a registrant's responsibility for recall, transportation, storage and disposal of canceled and suspended pesticides to registrations that he holds.

Paragraph (4) establishes rights to injunctive relief and penalties by the Administrator if the registrant of a suspended and canceled pesticide fails to comply with applicable regulations or orders regarding the handling of the pesticide.

Section 1602—Containers, rinsates, and other materials

Section 1602 further amends section 19 (7 U.S.C. 136q), subsection (a) by providing authority to the Administrator to establish requirements and procedures (A) to be followed by any person who stores or transports a pesticide container, a rinsate containing the pesticide and other material related to containing or collecting excess or spilled quantities for a pesticide the registration of which has been suspended or canceled, (B) to be followed by any person who disposes of stocks of such containers, rinsates or materials of a pesticide the registration of which has been suspended, and (C) for the disposal of stocks of such containers, rinsates or materials of a pesticide that has been canceled.

Nothing in section 1601 or 1602 is intended to supecede the authority of the Resource Conservation and Recovery Act of 1976 (42 U.S.C. 6901 et seq.). The Committee wishes to confirm that these amendments to section 19 shall apply prospectively to regulatory actions taken by the Administrator after the effective date of these amendments. These amendments shall not affect any obligation of the Administrator arising under section 19 is still pending, either administratively or judicially, on the effective date.

Section 1603—Pesticide containers

Section 1603 amends Section 19 (7 U.S.C. 136q) (as amended by sections 1601 and 1602 of [illegible] Act) by adding the following new subsections (e), (f), and (g):

Paragraph (1) of subsect[illegible]e) requires the Administrator to promulgate regulations for th[illegible]esign of pesticide containers that will promote safe storage and disposal of pesticides. The regulations must provide for containers that accommodate residue removal, rinsing, eliminate splashing and leakage, and facilitate safe refill and reuse of such containers.

Paragraph (2) mandates compliance with such regulations not later than five years after this subsection becomes effective.

Paragraph (1) requires the Administrator to develop procedures and standards for removal of pesticide residues from containers prior to disposal. Such procedures must include triple rinsing or equivalent removal techniques, reuse of containers, and disposal of rinsate and residues. Requirements for rinsing containers must be coordinated with those imposed under the Resource Conservation and Recovery Act of 1976 (42 U.S.C. 6901 et seq.).

The Administrator may exempt certain products intended for household use from the requirements of this subsection, provided that nothing in this subsection shall affect the authorities or requirements concerning such products under the Resource Conservation and Recovery Act of 1976. Similarly, nothing in this subsection shall affect the authorities or requirements concerning pesti-

cide containers under the Resource Conservation and Recovery Act of 1976.

Paragraph (2) requires a State to carry out an adequate program in compliance with this subsection within 5 years of the effective date of this subsection or lose its primary enforcement authority under section 26 and certification authority for pesticide applicators under section 4 of this Act.

Paragraph (1) of subsection (g) requires the Administrator to conduct a study of options regarding the recycling of pesticide containers, pesticide formulations that facilitate pesticide residue removal, and bulk storage facilities. The Administrator must consult with other Federal agencies, State agencies, industry and environmental groups, and assess the feasibility, costs and benefits of various options.

Under paragraph (2), the Administrator must report to the Congress regarding the results of the study no later than 2 years after the effective date of this subsection.

TITLE XVII—DELEGATION AND COOPERATION

Section 1701—Occupational safety or health authority

Section 1701 amends section section 22 of the Act (delegation and cooperation) by adding a new subsection (c) to provide that the Administrator, in exercising any authority under the Act, shall not, for the purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970, be deemed to exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health to the extent that the Administrator and the Secretary of Labor by agreement specify that the exercise of authority by the Administrator under the Act is not to be considered an exercise of statutory authority for purposes of section 4(b)(1). To ensure the safety and health of workers, the Administrator and the Secretary of Labor must seek to reach agreements and to coordinate the exercise of their statutory authority.

Section 4(b)(1) provides that provisions of the Occupational Safety and Health Act do not apply to working conditions of employees with respect to which other Federal agencies exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health.

The purpose of section 4(b)(1) is to prevent duplication of effort among Federal agencies charged with the protection of workers' safety and health. New subsection (c) retains the principle of 4(b)(1) while making it clear that the Department of Labor and the Environmental Protection Agency must enter into agreements to clarify their respective exercise of statutory authority.

Section 1702 further amends section 22 of the Act by adding a new subsection (d) concerning the use of determinations, findings, or guidelines made under other laws. Before the Administrator uses, under the Act, a determination, finding, or guideline that is made under another Federal or State law, the Administrator must consult with Federal or State authorities that issued the determination, finding, or guideline and must assure that the actions of the Administrator (1) are based on the best scientific and commer-

cial data available; and (2) have been formulated under procedures that afforded an opportunity for comment by affected parties.

TITLE XVIII—STATE COOPERATION, AID, AND TRAINING

SECTION 1801—COOPERATIVE AGREEMENTS

Section 1801 amends and makes technical modifications to subsection (a) of section 23 of the Act. As rewritten, subsection (a) authorizes the Administrator to enter into cooperative agreements and grants with States and Indian tribes to—

(1) delegate to any State or Indian tribe the authority to cooperate in the enforcement of the Act through the use of its personnel or facilities, train personnel of the State or Indian tribe to cooperate in the enforcement of the Act, and assist States and Indian tribes in implementing cooperative enforcement programs through grants;

(2) provide an amount equal to 50 percent of the anticipated cost of each State or Indian tribe, as proscribed under the cooperative agreements, of conducting training programs for the certification of applicators. Funds must be distributed among States and Indian tribes on a formula basis, as developed cooperatively between the Secretary of Agriculture and the Administrator; and

(3) provide an amount equal to 50 percent of the anticipated cost to each State or Indian tribe, as agreed under the cooperative agreements, of conducting pesticide certification and licensing programs, and in the case of a State, for administering the State certification plan approved under section 4(a) of the Act. Funds must be distributed among the States and Indian tribes on a formula basis as specified by the administrator.

There are authorized to be appropriated such sums as may be necessary for cooperative agreements and grants under the subsection.

TITLE XIX—AUTHORITY OF STATES

Section 1901—State regulation; household antimicrobial pesticides

Section 1901 redesignates and restates existing section 24(a) of the Act as new section 24(a)(1) and provides that a State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by the Act.

Section 1901 also amends existing section 24(a) by adding a new paragraph (2). Subparagraph (A) of new section 24(a)(2) applies to any house or garden pesticide where (1) the pesticide is a formulated end-use product; (2) the pesticide has been registered under section 3(c)(5) of the Act or reregistered under section 3A of the Act after the effective date of the bill; (3) the Administrator has determined that the product as registered or reregistered poses no significant toxicological concern; (4) the Administrator has published the determination of no significant toxicological concern in the Federal Register; (5) the registrant of the product has offered, at the time the registrant provides the final product label to the Administrator, to provide under the conditions of the Act to the ap-

propriate State authority any data submitted by the registrant to the Administrator in support of the registration; and (6) at least 45 days have elapsed from the date on which an application for State registration has been filed.

Subparagraph (B) of new section 24(a)(2) provides that except as provided in subparagraph (C) of new section 24(a)(2), a State may not prohibit any sale or use permitted under the Act of a pesticide described in subparagraph (A) of new section 24(a)(2) for which an application for State registration has been filed unless and until the State has finally acted on the application pursuant to applicable State law.

Subparagraph (C) of new section 24(a)(2) provides that paragraph (2) of new section 24(a) may not preclude a State from prohibiting the sale or use of a pesticide if the State requires in the State registration process additional toxicity data beyond that required by the Administrator. Paragraph (2) ceases to be effective 5 years after the date of the enactment of the bill.

Section 1902—State registrations

Section 1902 amends section 24(c) of the Act to require that, when a State provides a registration for additional uses of a Federally registered pesticide meet special local needs, the registration expires and is of no further effect (without further action by the Administrator) (1) at the end of the period, if any, provided as the duration of the registration by the State that approved it, or (2) ten days after the date the Administrator publishes in the Federal Register a notice stating that the State that issued the registration has informed the Administrator that the State no longer desires the registration to continue in effect.

Section 1902 further amends section 24(c) to add a new provision requiring the Administrator to establish criteria that define the conditions under which a special local needs registration may be disapproved, taking into account geographic patterns of use. (Note: Under current law, the Administrator has limited authority to disapprove any State special local needs registration during the first 90 days it is in effect).

Section 1903—Differences in usage and risk

Section 1903 amends section 24 of the Act to add a new subsection (d) relating to differences in usage and risks. New subsection (d) provides that in promulgating any regulations or policies pertaining to the sale or use of pesticides within a State, the State may take into account the difference in concept and usage between various classes of pesticides and the differences in environmental risk and the appropriate data for evaluating such risk between agricultural and nonagricultural pesticides.

TITLE XX—AUTHORITY OF ADMINISTRATOR

Section 2001—Congressional review

Section 2001 rewrites paragraph (4) of section 25(a) of the Act, which provides for review by Congress of rules and regulations issued under the Act. Current provisions, which provide for congressional veto of rules and regulations, are deleted. As rewritten,

paragraph (4) provides that the Administrator, simultaneously with the promulgation of any rule or regulation under the Act, must transmit a copy to the Secretary of the State and the Clerk of the House of Representatives. The rule or regulation may not become effective until 60 calendar days after the rule or regulation is transmitted.

Section 2002—Scientific advisory panel

Section 2002 makes a conforming amendment to section 25(d) of the Act regarding submissions to the Scientific Advisory Panel under new paragraph (8) of section 3(c) of the Act (as amended by section 213 of the bill). Section 2002 further amends section 25(d) to expand the panel from seven members to nine members and make the panel permanent.

Section 2003—Worker health and safety

Section 2003 amends section 25 of the Act by adding a new subsection (f) relating to worker health and safety.

Paragraph (1) of new subsection (f) requires the Administrator, as soon as practicable, to promulgate regulations that require the protection, as appropriate and necessary, of (1) employees who mix, load, or apply pesticides and (2) agricultural employees who work in pesticide-treated areas. The Administrator must promulgate regulations that provide for the training, as appropriate and necessary, of employees who mix, load, or apply pesticides. Any training requirement established by the Administrator may not apply to any person who is required to receive the training under new subsection (d) and (e) of section 4 of the Act (added by section 401 of the bill). The term "employees", as used in paragraph (1), does not include employees occupationally exposed to pesticides or pesticide residues as a result of the use of the pesticides on livestock or other animals.

Under paragraph (2) of new subsection (f), the Administrator must promulgate the regulations that require the protection, as appropriate and necessary, of employees (other than agricultural employees who mix, load, or apply pesticides or who work in pesticide-treated areas) not later than three years after the date of enactment of the bill.

The Administrator must provide six months for comments on the proposed regulations to be issued under paragraph (1) that apply to agricultural employees who mix, load or apply pesticides or who work in pesticide-treated areas, and promulgate these regulations not later than two years after the date of enactment of the bill.

Paragraph (3) of new subsection (f) provides that, not later than six months after the date of the publication of the notice of the proposed rulemaking issued for the regulations (described in the preceding paragraph) on agricultural employees who mix, load, or apply pesticides or work in pesticide-treated areas, the Secretary of Agriculture must submit to the Administrator a report on the impact, cost, and effectiveness of the regulations on the agricultural community, and submit a copy of the report to Congress.

Paragraph (4) of new subsection (g) requires the Administrator to transmit, simultaneously with promulgation, copy of the regulations issued under the paragraph (1) to the Secretary of the Senate

and the Clerk of the House of Representatives. The regulations may not become effective until 120 days after the date the regulations are transmitted. (NOTE: It is an unlawful act to violate these regulations under section 12 of the Act, as amended by section 1201 of the bill).

TITLE XXI—STATE PRIMARY ENFORCEMENT RESPONSIBILITY

Section 2101—Records

Section 2101 makes amendments to section 26(c) of the Act to conform with the amendments made by sections 701, 801, 802, 803 of the bill.

Section 2102—Expiration of State primary enforcement responsibility

Section 2101 amends section 26 of the Act by adding a new subsection (d) to provide that the primary enforcement responsibility of a State under the Act with respect to pesticide use violations expire on January 1, 1991, unless the Administrator determines that the State has the authority to impose civil and criminal penalties at least as stringent as those provided in section 14 of the Act.

TITLE XXII—FAILURE BY STATE TO ASSURE ENFORCEMENT OF STATE REGULATIONS

Section 2201—Authority for EPA action

Section 2201 amends the second sentence in subsection (a) of section 27 of the Act.

While section 26 of the Act provides for the States to have primary enforcement responsibility with respect to pesticide use violations, section 27 of the Act contains provisions for Federal action on violations when a State fails to ensure enforcement of pesticide use rules.

The second sentence of subsection (a) of section 27 currently provides that the Administrator may act on a pesticide use complaint or information if the State does not promptly commence appropriate enforcement action on the case within 30 days after receiving the complaint or information. As amended, the second sentence provides authority for the Administrator to act on a complaint or information if a State does not promptly initiate appropriate investigative action after receiving a referral from the Administrator or does not initiate appropriate enforcement action within 90 days after receipt of the referral.

TITLE XXIII—PESTICIDES IN GROUND WATER

Section 2301—Pesticides in ground water

Section 2301(a) redesignates section 31 of the Act as section 32 and inserts a new section 31 relating to the protection of ground water.

Subsection (a) of new section 31 requires the Administrator to publish and seek comment on criteria to determine whether a pesticide has the potential to leach into ground water. Such criteria

may include factors such as the intended use of the pesticide; the timing, rate, and method of application for the pesticide; the mobility of the pesticide in soil and water under various conditions; and the rates of degradation of the pesticide in soil and water under various conditions.

Each person seeking to register or reregister a pesticide under the Act must submit such data and information as the Administrator requires with respect to the potential for the pesticide to leach into ground water and the destination and method of transportation of the pesticide. At the time of registering or reregistering a pesticide (and using the criteria described above), the Administrator must determine whether the pesticide has the potential to leach into ground water.

If the Administrator determines that a pesticide has the potential to leach into ground water as described in this subsection or the pesticide has been detected at ground water sampling points in three or more locations, the Administrator also must determine whether monitoring data on the presence of the pesticide in ground water are required to register or maintain in effect an existing registration of the pesticide.

Subsection (b) of new section 31 provides for notification of pesticide detections. When a pesticide registrant obtains or learns of reliable analytical data that a pesticide (1) has been detected at any ground water sampling point and no ground water residue guidance level (GRGL) has been issued for the pesticide under section 1420 of the Public Health Service Act (the Safe Drinking Water Act), (2) has been detected at a ground water sampling point at a concentration higher than known previously to have been reported to the Administrator at such ground water sampling point, or (3) has been detected at any ground water sampling point at a concentration at or greater than 20 percent of the GRGL issued for the pesticide, the registrant must file a report containing such information within 15 working days. The report must be filed with the Administrator, the State in which the ground water sampling point is located, and the owner of the property in which the ground water sampling point is located, if known.

The report must contain information known to the registrant of the pesticide on the level of detection of the pesticide, frequency of detection of the pesticide, location (including depth) where the pesticide was detected, date of the pesticide detection, well construction if the pesticide was detected in a well, soil type where the pesticide was detected, and analytical method used to make the pesticide detection, including information on the precision, accuracy, and limits of the method of detection and any quality assurance and control procedures used in the pesticide detection.

On receiving information of a detection of a pesticide at any ground water sampling point, the Administrator must promptly review the information to determine the reliability of the detection and to determine whether further action should be taken to protect ground water.

Subsection (d) authorities ground water monitoring under certain circumstances. If the Administrator receives reliable analytical data indicating that (1) a pesticide has been detected in a drinking water well, (2) the concentration of the pesticide equals or exceeds

any ground water residue guidance level issued under subsection (d) for that pesticide, AND (3) the presence of the pesticide in the drinking water well may be the result of use of the pesticide in accordance with the labeling of the pesticide or widespread and commonly recognized practice involving the pesticide, and the Administrator may require the registrant of the pesticide detected to conduct such analysis of samples of ground water from the drinking water well involved as is necessary to determine whether the pesticide is present at a concentration that equals or exceeds such GRGL.

A monitoring requirement imposed under the preceding paragraph must be completed within 90 days of notice to the registrant. The procedures set forth in section 3(c)(2)(B) govern any monitoring requirement imposed.

If the Administrator determines that additional data on the presence of a pesticide in ground water are required to maintain in effect an existing registration of the pesticide, the Administrator may, under section 3(c)(2)(B), require the registrant of the prestiside to conduct ground water monitoring. The Administrator must consult with the Secretary of Agriculture, the heads of other appropriate Federal agencies, and the States concerning the design and scope of monitoring requirements imposed. Monitoring requirements imposed under this paragraph are subject to judicial review under section 16 of the Act.

The design and scope of the monitoring requirement should take into account all relevant information, including the magnitude and frequency of the detection of the pesticide involved, pattern of pesticide use and soil types involved in the detection, physical and chemical properties of the pesticide, rainfall patterns, well construction if the pesticide was detected in a well, rates of degradation, reliability and analytical accuracy of the detection, and results of State or other sponsored monitoring. To the extent feasible, monitoring should be at representative geographical and hydrogeological areas associated with locations and conditions of concern as determined by the Administrator.

Subsection (e) of new section 31 sets forth requirements for amending the registration of pesticides detected in ground water. Paragraph (1)(A) of subsection (e) requires that the Administrator determine, after reviewing reliable analytical data, whether there is a reasonable likelihood that the GRGL for a pesticide will be exceeded in drinking water wells in different localities. The Administrator must provide for notice and opportunity for public coment on any determination under this clause and shall publish the determination in the Federal Register.

If the Administrator determines that there is a reasonable likelihood of exceeeding such level in different localitites, the Administrator must promptly require amendments to the registration of the pesticide involved that are reasonably necessary to assure that the use of the pesticide in accordance with the amended registration will not cause the final GRGL to be exceeded in drinking water wells. Such determination must be made public.

If the Administrator proposes to require registration amendments, the Administrator must notify registrants of such amendments and must publish notice of the determination in the Federal

Register. Such notice must include the determination of the Administrator whether the presence of the pesticide in drinking water wells appears to have been the result of use of the pesticide in accordance with the labeling or widespread and generally recognized practice.

Paragraph (1)(B) sets forth parallel requirements for registration amendments based on pesticide detections in potential sources of drinking water, except that the Administrator is not required to, but may, make public a determination of "reasonable likelihood" of the exceeding the GRGL in potential sources of drinking water or publish notice of the determination in the Federal Register. In addition, the Administrator must meet the requirements of paragraph (1)(A), take into account information submitted by States on land and ground water use classification or other governmental actions that could affect when ground water may be used for drinking water, and consider the views of the Secretary of Agriculture, other heads of appropriate Federal agencies, and States as required in paragraph (2).

Paragraph (2) of subsection (e) provides that in taking action under paragraph (1), the Administrator must consult with the Secretary of Agriculture and the State where the pesticide involved has been detected in any ground water sampling point and each other State in which there is significant use of the pesticide. The Administrator must notify such State of the determination of the Administrator that there is a reasonable likelihood that the GRGL will be exceeded and must provide the State with all information relevant to this determination subject to section 10(h). A State must promptly provide the Administrator with information relevant to taking action under this section and must make recommendations regarding necessary registration amendments with respect to the State.

Paragraph (3) provides a presumption for meeting the "reasonable likelihood" test. Paragraph (3) provides that, for purposes of the registration amendments requirement, there shall be a presumption that there is a reasonable likelihood that a GRGL for a pesticide will be exceeded in drinking water wells if the pesticide is detected above 30 percent of the GRGL, unless considering other factors the Administrator determines, after notice and opportunity for public comment, that there is not such a reasonable likelihood.

Other factors include the circumstances surrounding the presence of the pesticide in ground water, taking into account all relevant information, the frequency and time of occurrence at the site of detection and elsewhere, use patterns, soil types, physical and chemical properties of the pesticide, rainfall patterns, well construction, analytical accuracy, and rates of degradation.

Paragraph (4) of subsection (e) provides that amendments to the registration of a pesticide may include limitations on the purposes for and location at which the pesticide may be used, considering factors such as environmentally sensitive areas and conditions; limitations on the rate at which the pesticide is applied; limitations on the time or frequency of pesticide use; limitations on the method of pesticide application, storage, handling, or disposal; reporting or other requirements, including label changes or changes in classification; requirements for the training or certification of pesticide

applicators or other persons using the pesticide; required site-specific responses; or any other requirement under the Act to ensure that the GRGL for such pesticide will not be exeeeded.

Paragraph (4) further provides that the amendments to the registration of a pesticide should, to the extent feasible, be directed to the same or similar uses of the pesticide, similar geographical and hydrogeological areas, and other similar conditions that led to the determination under subparagraph (A) or (B) of paragraph (1). In taking regulatory action under subsection (e), the Administrator may utilize recommendations provided by the States under paragraph (2). In requiring such amendments, the Administrator must consider the effect of any voluntary actions by registrants or other persons, including actions by the State to prevent the GRGL from being exceeded, and compliance with other environmental laws.

Under paragraph (5), if the Administrator has imposed registration amendments on the use of a pesticide according to subsection (e), the Administrator must—

(1) periodically review reliable analytical data on the occurrence of the pesticide at ground water sampling points representative of the locations at which the pesticide is used to determine whether such amendments are effective in meeting the requirement of paragraph (1);

(2) require additional registration amendments, if such amendments are necessary to assure the GRGL for such pesticide will not be exceeded in drinking water wells and potential sources of drinking water; and

(3) report to the Congress not later than January 31, 1990, and every 2 years thereafter, on whether any such initial or additional amendments have been effective in meeting the requirements of paragraph (1), and make the report available to affected States on request.

Paragraph (6) provides that registration amendments under paragraph (1) must be imposed in accordance with the procedures required by the Act.

Subsection (f) of new section 31 sets forth requirements for responding to contamination of drinking water well. Paragraph (1) sets forth requirements for State action. If the Administrator determines that a pesticide is present in a concentration that exceeds the final GRGL and that the presence of the pesticide in a drinking water well may be the result of the use of the pesticide in accordance with the labeling on the pesticide or as a result of widespread and commonly recognized practice involving the pesticide, the Administrator must notify the State in which the drinking water well is located of the determinaton, and provide the State, subject to section 10(h), with all information relevant to the determination.

Such State must take action within 90 days of such notification to prevent potential adverse effects on human health and the environment from such pesticide. In taking such action, the State must take appropriate action regarding the sale or use of the pesticide detected at such drinking water well to bring and retain concentrations of the pesticide at such drinking water well at or below the final GRGL applicable to the pesticide.

Paragraph (2)(A) of subsection (f) sets forth requirements for action by the Administrator if the State does not act. If a State

does not have the authority to take action required by paragraph (1) with respect to a pesticide detected in a drinking water well or fails to take such action within the time period prescribed by such paragraph, a pesticide is present in a drinking water well in the State at a concentration that exceeds the final GRGL, and the presence of the pesticide may be the result of use in accordance with the labeling or of widespread and commonly recognized practice, the Administrator must take appropriate action under the Act to bring and retain the concentration detected at such drinking water well at or below the final GRGL applicable to the pesticide. The Administrator may take such other action under the Act as the Administrator considers necessary to prevent potential adverse effects on human health and the environment from the pesticide at such drinking water well.

Paragraph (2)(B) requires the Administrator to publish notice of the action in the Federal Register and take appropriate steps to inform all registrants, potentially afffected persons, and interested members of the public. Such notice must specify the factual findings and conclusions relied on in support of the decision.

Paragraph (2)(C) provides that any person adversely affected by an action or failure to act under paragraph (2) must have an opportunity for an expedited hearing, pursuant to the procedures set forth in section 6(c)(2), to determine whether the action was taken in accordance with this paragraph or whether the Administrator was required to take action.

Paragraph (2)(D) provides that notwithstanding any other provision of the Act, a hearing must be held and determination made under subsection (h) within 75 days after receipt of the request for such a hearing.

Paragraph (2)(E) requires the Administrator to provide reasonable pesticide ingredient characteristics, predictive modeling, exposure and other relevant subjects. In addition, the Administrator must provide information, to the extent reasonably available, on the alternative methods of pest control and on agricultural or other management practices that could minimize the presence of pesticides in ground water.

Subsection (i) of new section 31 authorizes the Administrator, on receiving reliable analytical data that a pesticide has been detected above the GRGL in ground water in a drinking water well or potential source of drinking water, to initiate a public interim administrative review under section 3(c)(8) to determine whether the pesticide may cause unreasonable adverse effects on the environment from such use.

Subsection (j)(1) requires the Administrator to enter into a memorandum of understanding with the Secretary of Agriculture, the Secretary of Commerce, and the Secretary of the Interior for the purpose of developing information management systems and other techniques designed to make available information more useful to State and local officials and agricultural procedures, applicators, and other persons using the pesticide information on the soil, hydrology, climate, and other characteristics or specific sites of pesticide application to be used by such officials and users in developing practices and making application decisions that will prevent the contamination of ground water by pesticides.

Subsection (j)(2) provides for the establishment of a council, under the direction of the Administrator, to assist the Environmental Protection Agency in develop a site-specific pesticide information system. The council must consist of experts on information management who have experience with information retrieval from the EPA, the National Agricultural Library, the Soil Conservation Service, the U.S. Geological Survey, and the National Oceanograpic and Atmospheric Administration. The council is required to—

(1) review existing information retrieval and referral services that may be used to access information on soil, hydrology, climate and other characteristics at specific sites important to pesticide application;

(2) determine what information relevant to making site-specific pesticide decisions is available directly from existing data banks; and

(3) based on these determinations develop and submit to the Administrator a plan for an information management system that would direct and assist users in gaining access to site-specific information available in printed and electronic form.

Under subsection (j)(3), the Administrator is required to take the plans developed by the council into consideration when developing the site-specific pesticide information management system.

Subsection (j)(4) provides that the subsection shall take effect to the extent that appropriations are made for it. There are authorized to be appropriated $2,500,000 to carry out subsection (j) for each of the fiscal years 1988 through 1992.

Subsection (k) of new section 31 provides that nothing in section 31 shall shall limit the authority of the Administrator or of any State under other provisions of the Act of any other law.

Subsection (b) of section 2301 of the bill amends Part C of title XIV of the Public Health Service Act (the Safe Drinking Water Act) by inserting after section 1428 (42 U.S.C. 300h-7) a new section 1429. (The Safe Drinking Water Act requires EPA to establish drinking water regulations for public water systems that will protect health to the extent feasible, using generally available treatment techniques and other means, taking cost into consideration. The principal enforcement vehicle is primary regulations that specify maximum containment levels (MCLs) for pollutants that may cause an adverse health effect.)

Subsection (a) of new section 1429 provides for the issuance of ground water residue guidance levels (GRGLs). Paragraph (1) authorizes the Administrator to issue a GRGL for a pesticide registered under the FIFRA. Paragraph (2) requires the Administrator to issue a GRGL for a pesticide whenever the Administrator registers or reregisters a pesticide under FIFRA if the Administrator determines that the pesticide has the potential to leach into ground water.

Paragraph (3) of subsection (a) further requires the Administrator to issue a GRGL for a pesticide if (1) based on reliable analytical data, the pesticide has been detected at ground water sampling points in three or more different geographical areas, (2) based on reliable analytical data, the pesticide has been detected in a drinking water well or well field that serves a population of over 500

people, or (3) a Federal agency or a State petitions that Administrator to set a GRGL.

Paragraph (1) of subsection (b) of new section 1429 provides that if the Administrator has promulgated or promulgates a maximum containment drinking water regulations for public water systems) that applies to a pesticide, the GRGL required under subsection (a) for the pesticide must be set at such level within 30 days of being required under such section.

Paragraph (2)(A) of subsection (b) provides for establishing a GRGL in the absence of a MCL. If a MCL that would be applicable to a pesticide for which a GRGL is required by subsection (a) has not been established under section 1412, the Administrator is authorized to use a health advisory level in establishing such GRGL. (Health advisory levels serve as informal technical guides to assist Federal, State and local officials responsible for protecting public health when emergency spills or containment occurs. They are not legally enforceable Federal standards and are subject to change as new information becomes available.)

Paragraph (2)(B) provides that the GRGL established under this paragraph must reflect the level of the pesticide in drinking water at which no know or anticipated adverse effect on the health of persons occur, the need for an adequate margin of safety, the nature of the toxic effects caused by the pesticide, and the validity, completeness, and adequacy of data about the pesticide.

Paragraph (2)(C) requires the GRGL established under this paragraph be set at the limit of detection if all required chronic, oncogenicity, reproduction, or teratogenicity data are absent or invalid for the pesticide. If any required chronic, oncogencity, reproduction, or teratogenicity data are absent or invalid for the pesticide, paragraph (2)(D) requires the GRGL established to include an additional margin of safety that takes into account the absence of such data.

Subsection (c) of new section 1429 provides for a procedure for setting ground water residue guidance levels. Paragraph (1) of subsection (c) requires the Adminstrator, before issuing a final GRGL, to publish an interim GRGL for the pesticide in the Federal Register and allow public comment for at least 30 days. During the public comment period the Administrator must invite comment on such level from the Secretary of Agriculture.

Paragraph (2) of subsection (c) provides that if the Administrator is required under subsection (a) to issue a GRGL for a pesticide and the GRGL is to be issued pursuant to subsection (b)(2) (based on a health advisor level), the Administrator must issue an interim GRGL within 30 days after the requirement to issue the GRGL takes effect.

Paragraph (3) of subsection (c) requires the Administrator to establish a final GRGL within 3 months after establishing an interim GRGL. Until a final GRGL is established under subsection (a) for a pesticide, an interim GRGL established for the pesticide remains in effect.

Subsection (d) of new section 1429 authorizes the Administrator to revise a GRGL for pesticide. The Administrator must allow at least 30 days for public comment on any proposed revision.

Subsection (e) of new section 1429 provides that an interim GRGL may not be subject to judicial review before the expiration of 3 months after its issuance. Judicial review of any final GRGL or failure to establish an interim of final GRGL is governed by section 1448 of the Safe Drinking Water Act. A GRGL established under subsection (b)(1) (based on a maximum contaminant level) may not be subject to judicial review.

TITLE XXIV—AUTHORIZATION FOR APPROPRIATIONS

Section 2401—Authorization for appropriations

Section 2401 amends section 33 of the Act (as redesignated by section 2301 of the bill) to authorize to be appropriated to carry out the Act (other than section 23(a) and section 31) $103,363,500 for fiscal year 1988, of which not more than $13,735,500 must be available for research; $112,414,200 for fiscal year 1989, of which not more than $14,343,6000 must be available for research; $116,673,400 for fiscal year 1990, of which not more than $14,978,200 must be available for research; $123,305,800 for fiscal year 1991, of which not more than $15,625,900 must be available for research; and $131,808,700 for fiscal year 1992, of which not more than $16,300,100 must be available for research.

TITLE XXV—OTHER PROVISIONS

Section 2501—Liability for lawful application

Section 2501 creates an exemption for agricultural producers from certain types of environmental liability under certain conditions.

Paragraph (1) of subsection (a) defines the source of such liability as arising from the release or threatened release of a pesticide into the environment or damages incurred with respect to such release or threatened release in connection with the production of an agricultural commodity. The paragraph further provides that liability shall not be imposed on an agricultural producers if, as certified by the producer to the Administrator, the application was in compliance labeling instructions and applicable law unless the producer acted negligently, recklessly, or with the intent to misuse such pesticide.

Under paragraph (2) of subsection (a) "agricultural producer certification" includes a statement of the approximate date of application, name of the pesticide, and rate and location of application. Such statement shall be based on records or other information proximate to the pesticide application.

Paragraph (3) of subsection (c) states that the liability provisions of paragraph (1) shall not preempt, assign or transfer liability under any State statutory or common law, affect federal environmental laws that prohibit application of a pesticide or its release into the environment or create a new liability or confer a private right of action of any person under the Federal Insecticide, Fungicide and Rodenticide Act or any other Federal law.

Subsection (b) defines the following terms applicable to this section:

Paragraph (1) defines "agricultural producer" as a nongovernmental producer of an agricultural commodity who uses or supervises the use of any pesticide for the production of such commodity on property owned or rented by the producer or producer's employer, or without compensation assists another such producer with the application of a pesticide on such producer's land.

Paragraph (2) defines "application" as actions relating to the mixing, loading, applying, storage, disposal and farm-to-farm transport of the pesticide by an agricultural producer.

Paragraph (3) provides that "damages", "release", and "environment" shall be defined as these terms are defined under the Comprehensive Environmental Response, Compensation and Liability Act of 1980.

Paragraph (4) includes under "Federal environmental law" the Comprehensive Environmental Response, Compensation and Liability Act of 1980, the Federal Water Pollution and Control Act, the Solid Waste Disposal Act, title XIV of the Public Health Service Act and section 31 of the Federal Insecticide, Fungicide and Rodenticide Act.

Paragraph (5) defines "liability" as including any obligation to clean up, respond to, or otherwise abate a release.

Paragraph (6) states that "pesticide" shall have the meaning assigned under section 2(u) of the Federal Insecticide, Fungicide, and Rodenticide Act.

Section 2502—IR4 program

Section 2502 amends section 2(c) of the Act of August 4, 1965 (7 U.S.C. 450i(c)), relating to agricultural research grants, to require the Secretary of Agriculture to provide support under such Act for the interregional project number 4 program (commonly referred to as the "IR-4 program"), which generates health and safety data on minor use pesticides that are used for agricultural purposes.

Section 2503—Restoration of patent term for certain agricultural and chemical products

Section 2503(a) adds a new section 158 to chapter 14 of title 35 of the United States Code.

Subsection (a) of new section 158 provides that the term of a patent that claims a product subject to a regulatory review period or a method for using or manufacturing such a product must be extended in accordance with new section 158 from the original expiration date of the patent if (1) the owner of record of the patent notifies the Commissioner in compliance with subsection (d), (2) the product was subject to a regulatory review period before its commercial marketing or use, (3) the patent term was never previously extended, (4) the patent term had not expired prior to the above mentioned notification to the Commissioner, and (5) the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred, or in the case of a patent that claims a method of manufacturing the product that primarily uses recombinant DNA or hybridoma technology in the manufacture of the product, the permission for the commercial marketing or use of

the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent.

Subsection (b) of new section 158 limits the rights derived from any claim of an extended patent (1) in the case of a patent that claims a product, to any use approved for the product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred, (2) in the case of a patent that claims a method of using a product, to any use claimed by the patent and approved for the product before the expiration of the term of the patent under the provision of law under which the application regulatory review occurred, (3) in the case of a patent that claims a method of manufacturing a product, to the method of manufacturing as used to make the product.

Subsection (c)(1) of new section 158 provides that the term of a patent must be extended by the time equal to the regulatory review period that occurred after the patent was granted. This extension, however, is subject to several additional limitations.

Paragraph (1) of subsection (c) of new section 158 provides that the patent must be extended by the time equal to the regulatory review period that occurred after such patent was granted, except that no patent term may be extended for more than 5 years, and no term of any extended patent may exceed 17 years from the date the product for which the patent was issued was first permitted to be commercially marketed or used. If the regulatory review period began but has not ended by the date of enactment, the period of extension for the patent may not exceed 2 years. If, however, the regulatory review period has ended before enactment of new section 158, the patent term may not be extended.

Paragraph (2)(A) of subsection (c) provides that any regulatory review period that is to be applied for purposes of extending the patent must be reduced by certain periods during which applications for premarket approval were made under relevant statutes, but not accepted by the relevant agencies because the applications did not contain sufficient data or information. However, if during such period the product sponsor conducts a major health or environmental effects test, the period during which such test is conducted may not be excluded.

Paragraph (2)(B) of subsection (c) provides that any regulatory review period to be applied for purposes of patent term extension would further be reduced by any period determined under subsection (e) during which the applicant for the patent term extension did not act with due diligence.

Paragraph (3) of subsection (c) provides that not more than one patent may be extended for the same regulatory review for any product.

Paragraph (4) of new section 158(c) provides that for purpose of the extension of a patent term related to a pesticide, all formulations of the pesticide containing the identical active ingredient must be considered the same pesticide, and no pesticide may be the subject of more than one patent extension.

Subsection (d) of new section 158 sets forth the procedures to be followed in seeking and obtaining an extension of a patent term, and specifies the information which must be submitted to the Com-

missioner of Patents and Trademarks. Subsection (d) requires that within 60 days after termination of a regulatory review period, the owner of record of the patent or its agent must notify the Commissioner that the regulatory review period has ended. Notification by the product sponsor to the Commissioner must be in writing and must (1) identify the Federal statute under which the regulatory review occurred; (2) state the dates on which the regulatory review began and ended and identify the event that caused such period to begin; (3) identify the product for which regulatory review was required; (4) state that the requirements of the statute under which regulatory review occurred were satisfied so that commercial marketing or use of the product is not prohibited under the Federal statute which provided for the regulatory review in question; (5) identify the patent and any claim thereof to which the extension is applicable, identify any uses previously authorized, and state that the term of the patent has never been extended under this section, and that no other patent had been extended on the basis of the same regulatory review period; and (6) include any other information which the Commissioner may require.

Subsection (e)(1) provides that within 60 days after submittal of the extension notification, the Commissioner must notify the Secretary of Agriculture if the patent claims a plant or plant product or a method of using or manufacturing a plant or plant product, and the Administrator of the Environmental Protection Agency if the patent claims a pesticide subject to the FIFRA, a chemical substance or mixture subject to the Toxic Substances Control Act (15 U.S.C. 2601 et seq.), or method of using or manufacturing such a pesticide, substance, or mixture, of the extension notification and also must submit a copy of the extension notification to the Secretary or Administrator.

Not later than 30 days after reciept of the copy of the extension notification from the Commissioner, the Secretary or Administrator receiving the notice must review the dates contained in the notification and determine the applicable regulatory review period for the particular product in question. The Secretary or Administrator must notify the Commissioner of the detemrination and publish notice of the determination in the Federal Register.

Paragraph (2) of subsection (e) provides for the determination of the product sponsor's due diligence during the regulatory review period on the basis of a petition submitted to the Administrator.

Subparagraph (A) of paragraph (2) provides that if a petition is submitted to the Secretary or Administrator not later than 180 days after the publication of a determination of the applicable regulatory review period under paragraph (1) on which it may reasonably be determined that a product sponsor did not act with due diligence during an applicable regulatory review period, the Secretary or Administrator must, in accordance with regulations promulgated by the Secretary or Administrator, determine if the product sponsor acted with due diligence during the applicable regulatory review period. The Secretary or administrator must make such determination not later than 90 days after the reciept of a petition. The Administrator may not delegate the authority to make such determination to an office below the Assistant Administrator for Pesticides and Toxic Substances.

Subparagraph (B) of paragraph (2) requires the Secretary or Administrator making the determination to notify the Commissioner of the determination and to publish in the Federal a notice of such determination, together with the factual and legal basis for such determination. Any interested person may request, within the 60-day period beginning on the publication of a determination, the Secretary or Administrator in question to hold a hearing on the determination. Such hearing must be an informal hearing that is not subject to sections 554, 556, or 557 of title 5, United States Code. If such a request is made within such period, the Secretary or Administrator must hold such hearing not later than 30 days after the date of the request, or at the request of the person making the request, not later than 60 days after such date. The Secretary or Administrator who is holding the hearing must provide notice of the hearing to the product sponsor and to any interested person and provide the product sponsor and any interested person an opportunity to participate in the hearing. Within 30 days after the completion of the hearing, such Secretary or Administrator must affirm or revise the determination that was the subject of the hearing and notify the Commissioner of such affirmation or any revision of the determination and must publish such affirmation or revision in the Federal Register.

Subparagraph (C) of paragraph (2) provides that failure of a product sponsor to act with due diligence during a regulatory review period may not be a defense in any action involving the infringement of the patent in question.

Subparagraph (D) of paragraph (2) provides that in a proceeding under this paragraph, the Secretary or Administrator may take into consideration the failure of a product sponsor to submit data that the product sponsor knew or reasonably should have known was necessary to support an application or notice described in paragraph (4) for subsection (g).

Subparagraph (E) of paragraph (2) defines the term "due diligence" for purposes of paragraph (2) to mean that degree of attention, sustained directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.

Subsection (f)(1) of new section 158 requires the Commissioner to determine whether a patent is eligible for extension in accordance with the requirements of subsections (a) and (d). Such a determination may be based solely on the representations contained in the notification provided by the product sponsor under subsection (d) If the Commissioner determines that a patent is eligible for extension, and on receipt of a final determination of the applicable regulatory review period, the Commissioner must issue to the patent owner of record a certificate of extension of the patent, under seal, for the period prescribed in subsection (c). The certificate of extension must be recorded in the official file of the patent and considered part of the original patent. A notice of the extension must also be published in the Official Gazette of the Patent and Trademark Office.

Subsection (f)(2) provides that if the patent term for which a notification has been submitted under subsection (d) would expire before a certificate of extension is issued or denied under para-

graph (1), the Commissioner must extend, until such determination is made, the patent term for periods of up to 1 year if the Commissioner determines that the patent is eligible for extension. Such periods of extension must not exceed the regulatory review period calculated from the information provided in the notification submitted under subsection (d).

Subsection (g) defines terms used in new section 158 as follows:

Paragraph (1) defines the term "product" to mean any pesticide subject to regulation under FIFRA; any chemical substance or mixture subject to regulation under the Toxic Substances Control Act; or any plant or plant product that is genetically altered, is defined as a plant pest or potential plant pest under the Federal Plant Pest Act, and is subject to regulation under such Act.

Paragraph (2) defines the term "major health environmental effects test" to mean an experiment or study to determine or evaluate health or environmental effects that requires at least six months to conduct, not including any period for analysis or conclusions, and the data from which is submitted to receive permission for commercial marketing or use.

Paragraph (3) defines the term "product sponsor" to mean any person who, with the consent of the patent owner, initiates testing or investigation, claims an exemption, or submits an application or notice described in paragraph (4).

Paragraph (4) defines the term "regulatory review period" as follows:

Subparagraph (A) defines the regulatory review period with respect to pesticides regulated under the Act. The term means the sum of (1) the period beginning on the earlier of the date the product sponsor (A) initiates a major health or environmental effects test on such pesticide, or (B) requests, in accordance with regulations issued by the Administrator, the grant of an experimental use permit for the pesticide under section 5 of the Act and ending on the date an application is submitted for registration of such pesticide pursuant to section 3 or such Act; and (2) the period beginning on the date an application is submitted, in accordance with regulations issued by the Administrator, for registration of such pesticide pursuant to section 3 of the Act and ending on the date such pesticide is first registered, either conditionally or fully, under that section.

Subparagraph (B) defines the "regulatory review period" for chemical substances or mixtures subject to regulation under the Toxic Substances Control Act as follows. For a chemical substance or mixture that is subject to a rule requiring testing under section 4(a) of the Toxic Substances Control Act, the term means a period commencing on the date the product sponsor has initiated the testing required in such rule and ending on the expiration of the notice period for such chemical substances or mixture under section 5 of that Act, or if an order or injunction is issued under section 5(e) or 5(F) of that Act, the date on which such order or injunction is dissolved or set aside. For a chemical substance or mixture that is not subject to a testing rule under section 4 of that Act, the term means a period commencing on the earlier of the date the product sponsor (A) submits, in accordance with regulations issued by the Administrator, a notice under section 5 of such Act, or (B)

initiates a major health or environmental effects test on such chemical substance or mixture, and ending on the expiration of the notice period of such substance under section 5 of that Act or if an order or injunction is issued under section 5(e) or 5(f) of such Act, the date on which such order or such injunction os dissolved or set aside.

Subparagraph (C) of paragraph (4) provides that with respect to a product that is a plant or plant product, the term "regulatory review period" means the period beginning on the date an application is submitted under section 103 of the Federal Plant Pest Act for permission to move the plant or plant product in interstate commerce and ending on the date such application is approved.

Subsection (h) of new section 158 provides that if information submitted during a regulatory review period by a product sponsor which is considered a trade secret or confidential commercial or financial information under the law which mandates the regulatory review, the information may only be disclosed under new section 158 in accordance with such law. However, the Administration may disclose information necessary to publish a notice.

Subsection (i) of new section 158 authorizes the Commissioner, the Administrator and the Secretary of Agriculture to establish fees to cover the costs of carrying out their respective duties and functions under new section 158.

Subsection (j) provides that new section 158 shall cease to be in effect on the expiration of 15 years after the date of the enactment of the section, except that section 158 shall continue to apply to any patent that claims a product subject to a regulatory review period, a method for using such a product, or a method of manufacturing such a product if the patent was issued before the expiration of 15 years after such date.

Section 2503(b) makes a conforming amendment by inserting "or 158(e)" after "(2)" in the last sentence of section 282 of title 35, United States Code.

Section 2503(c) amends the analysis for Chapter 14 of title 35 of the United States Code to include a new heading for section 158.

Section 2503(d), which concerns the infringement of pesticide patents, adds a new paragraph (5) to section 271(e) of title 35 of the United States Code.

Subparagraph (A) of new paragraph (5) states that, except as provided in subparagraph (B), during the last 2 years of the term of a patent relating to a pesticide (including a patent that claims the pesticide, a method for using the pesticide, or a method of manufacturing the pesticide) that is or has been registered under the Act, or that is marketed with the permission of the patent holder, it may not be an act of infringement of the patent (1) to make, use, or sell the pesticide solely for testing reasonably related to the development and submission of data to comply with such Act; or (2) to obtain a tolerance or an exemption from a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) or (3) to obtain a food additive regulation under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348).

Subparagraph (B) provides that subparagraph (A) of new subsection (e) applies only to the first patent issued for a pesticide, a method for using a pesticide, or a method of manufacturing a pesti-

cide that makes the unlicensed manufacture, use, or sale of the pesticide a patent infringement. Subparagraph (A) may not apply to a patent that claims a method of manufacturing a pesticide that uses recombinant DNA or hybridoma technology in the manufacture of the pesticide.

Subparagraph (C) provides that it is an act of infringement for any person, other than the patent holder or the licensee of the patent, to submit an application for registration under the Act or under section 408 or 409 of the Federal Food, Drug, and Cosmetic Act for a pesticide covered by the first composition of matter patent, method of use patent, or method of manufacturing patent issued for the pesticide before expiration of such patent.

Subparagraph (D) provides that for purposes of paragraph (5), each formulation of a pesticide containing the identical active ingredient must be considered the same pesticide.

Section 2504—Tolerance for agricultural commodities

Section 2504 amends section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) by adding new subsection (p).

Paragraph (1) of new subsection (p) provides that if the registration of each pesticide containing a specific active or inert ingredient registered for use on a particular raw agricultural commodity (1) has been canceled by the Administrator under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), (2) has been canceled voluntarily under FIFRA, or (3) has been withdrawn voluntarily under FIFRA; due in whole or in part to dietary risks to humans, the Administrator must revoke any tolerance established under subsection (b) for residues of such pesticide chemical in or on such commodity or any exemption from the need for such tolerance established under subsection (c). Such action must be taken not later than 60 days after the effective date of such cancellation or after receipt of information of voluntary withdrawal. In revoking a tolerance or an exemption from a tolerance, the procedures required under section 553 of title 5, United States Code, must be used.

The effective date of a revocation may be delayed to permit distribution in commerce of food that bears residues of the active or inert ingredient as the result of (1) the use of the canceled pesticide before the date of its cancellation; (2) the use of existing stocks of such pesticide authorized under the order canceling the registration of the pesticide; or (3) unavoidable residual environmental contamination.

Paragraph (2) of new subsection (p) provides that if the registration of each pesticide containing a specific active or inert ingredient registered for use on a particular raw agricultural commodity has been suspended by the Administrator under FIFRA due in whole or in part to dietary risks to humans, the Administrator must suspend any tolerances established under subsection (b) of section 408 for residues of such pesticide chemical in or on such commodity or any exemption from the need for such tolerance established under subsection (c) of section 408. Such action must be taken not later than 60 days after the effective date of such suspension. However, the effective date of the suspension of the tolerance may be delayed to permit distribution in commerce of food that

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bears residues of the active or inert ingredient as the result of (1) the use of the suspended pesticide before the date of its suspension; (2) the use of existing stocks of such pesticide as authorized under the order suspending the registration of the pesticide; or (3) unavoidable residual environmental contamination.

In suspending a tolerance or an exemption from a tolerance, the procedures required under section 553 of title 5, United States Code, must be used. The suspension of a tolerance or an exemption from the tolerance for a pesticide chemical shall be effective as long as the registration of the pesticide to which the tolerance or exemption is applicable is suspended under FIFRA. If the registration of the pesticide ceases to be suspended and is not canceled under such Act, the Administrator must rescind any such suspension of a tolerance or exemption.

Under paragraph (3) of new subsection (p), at the time the Administrator makes a determination under section 3A(h)(2) (phase five of reregistration) of FIFRA regarding an ingredient of a pesticide, any tolerance established under subsection (b) for residues of a pesticide chemical that is or contains such ingredient or any exemption from the need for such a tolerance established under subsection (c) or a food additive regulation for residues of a pesticide chemical established under section 409, shall be reassessed.

Paragraph (3) further provides that at the time the Administrator makes a determination under phase five of reregistration, the Administrator must make a determination whether such tolerance, exemption from tolerance, or regulation meets the requirements of the Act, and confirm, establish, amend, or revoke such tolerance, exemption, or regulation in accordance with the requirements of this section.

Any tolerance, exemption, or regulation that is confirmed, established, or amended as described in the previous paragraph may not become effective until the Administrator determines that a practical method for detecting residues in or on food or feed is available in order to enforce such tolerance, exemption, or regulation.

Under paragraph (4) of new subsection (p), the Administrator, by regulation, may reasonably limit the application of a revocation or suspension of a tolerance or exemption from a tolerance to prevent the imposition of restrictions on the imports of a particular agricultural commodity from a particular country. However, no such limitation may be effected unless the Administrator determines (1) the tolerance or exemption satisfies the criteria of subsection (b) or (c) of section 408 of the Food, Drug, and Cosmetic Act; and (2) there is not available an effective alternative pesticide that may legally be used on the particular agricultural commodity in such country.

Section 2505—Biotechnology study

Section 2505 authorizes a biotechnology and integrated pest management study. The study will consider the potential of biotechnology to integrated pest management practices designed to reduce this country's dependence on traditional chemical pesticides and protect farmworkers, groundwater, and food from dangerous contamination.

The purpose of this study is to direct the National Research Council to investigate the state of USDA research on biotechnology

alternatives to synthetic pesticides and determine the how to best allocate USDA resources in this area. It is the intent of the Committee that the research findings of this study will complement the information provided in the pending National Research Council's report, *The Role of Alternative Farming Methods in Modern Production Agriculture.* A close and coordinated examination by the National Research Council of alternative farming methods with biotechnology developments should provide the information needed to systematically reduce our use of synthetic pesticides.

Paragraph (1) of subsection (a) requires the Administrator of the Environmental Protection Agency, working in conjunction with the Secretary of Agriculture, to study the potential contributions of biotechnology to reduce domestic reliance on, and human exposure to pesticides.

Paragraph (2) of subsection (a) requires that the study concentrate on those crop uses of pesticides known or thought to be contributing most heavily to the dietary exposure and risks associated with the use of pesticides.

Paragraph (1) of subsection (b) provides that the study be organized by major crop and major type of pest problem requiring pesticide applications. A study organized in this manner will give farmers, USDA, and Congress an analysis of where our biotechnology research efforts are currently focused.

Paragraph (1) of subsection (b) also provides that the study assess the science and technology development that has, or may, lead to viable biological or genetic alternatives, including traditional plant breeding, to broadly toxic pesticides. This will give farmers, USDA, and Congress a realistic evaluation of how close we are to field implementation of biotechnology alternatives. The study should also include an explanation of the nature of alternative control practices and estimate the timing and economic consequences of the adoption of new biotechnology-based or facilitated pest control practices.

The analysis should explore the relationship of biotechnology to other alternative agricultural practices for the reduction of synthetic pesticides such as crop rotations, tillage practices, and biological contols and estimate the viability of a multi-faceted sustainable agriculture system for pest control by major crop and major type of pest problem.

Paragraph (2) of subsection (b) provides that a comparative analysis of the ecological and human health risks associated with the use of bioengineered pesticides and plants be made with respect to the ecological and human health risks associated with the use of synthetic chemicals. Biotechnology does not necessarily mean safer or better products. It is not the Committee's intent to substitute one technology for another if it fails to meet all safety requirements.

Paragraph (3) of subsection (b) provides that the study analyze the extent to which current procedures of the Federal government provide for adequate review and timely registration and adoption of safer biological and biotechnological pest control agents and pest control systems. The study should consider whether adequate ecological data is required for approval of biological and biotechnological pest control agents. Given the extreme importance of finding al-

ternatives to several pesticides, there may be methods to facilitate the consideration of biological or biotechnological alternatives by the regulatory system. Among the several possibilities, the study should consider the FDA model where a critically needed drug is reviewed prior to other pending products.

Paragraph (4) of subsection (b) provides that the study recommend possible changes in regulatory, commodity, or conservation policy, law, or regulations that could facilitate adequate review and timely adoption of improved pest control technologies.

Paragraph (5) of subsection (b) provides that the study survey ongoing publicly funded agricultural research programs to determine the extent to which new biotechnological research efforts are focused on discovering safer pest control technologies for those crops and pests that are more important in terms of preventing human exposure to pesticides. Currently the Department of Agriculture spends less than 7% of its annual research budget on biotechnology. The Joint Council on Food and Agricultural Sciences in "FY 1989 Priorities for Research, Extension, and Higher Education," stressed the importance of expanding current USDA biotechnology activities. This study will provide the analysis to better understand how to recognize and supplement the Department's research budget to ensure that American farmers are provided with the alternative farming information they need.

Paragraph (6) of subsection (b) provides that the study assess the institutional opportunities to better coordinate the ongoing regulatory actions and policies with agricultural research and extension education policies and activities. The National Resources Council's 1987 report, "Agricultural Biotechnology, Strategies for National Competitiveness," found that the federal government "has not addressed the long-term needs and policy concerns of integrating biotechnology into agricultural research and technology. Short-term management approaches jeopardize the fragile U.S. competitive advantage in biotechnology." This study should build on the 1987 analysis and recommend changes in research policy.

Paragraph (7) of subsection (b) provides that the study examine the possible human risks and regulatory issues associated with the consumption of food derived from plants and that have been bioengineered to have an elevated level of some natural chemical or constituent that helps protect the plant from insects, plant pathogens, nematodes, viruses, or other diseases or pests.

Paragraph (8) of subsection (b) provides that the study explore the feasibility of setting priorities for research in the areas of disease and insect biology at land grant universities and agricultural experiment stations as a means of reducing pesticide use in agriculture. Groundwater problems, food contamination, and the high costs to farmers for pesticides makes it exigent that the agricultural land grant system research alternative farming systems.

Paragraph (1) of subsection (c) directs the Administrator of the Environmental Protection Agency to seek the assistance of the Board of Agriculture of the National Research Council of the National Academy of Sciences in carrying out the study.

Paragraph (2) of subsection (c) provides that no later than February 15, 1989, the National Research Council must submit to the House Agriculture Committee and the Senate Agriculture, Nutri-

tion and Forestry Committee a preliminary report that includes preliminary study results and highlights any budget-related issues or recommendations.

Paragraph (3) of subsection (c) provides that the final study report be submitted to the House Agriculture Committee and the Senate Agriculture, Nutrition, and Forestry Committee no later than March 1, 1990.

Subsection (d) of Section 2505 authorizes the necessary sums to conduct the study to be appropriated to the Environmental Protection Agency for use by the National Research Council of the National Academy of Sciences.

It is the Committee's hope that biotechnology will expand the list of pest control choices in the future, and reduce the costs for our farmers. Much more information is needed on the potential of biotechnology to contribute to integrated pest management systems. This study will provide the needed guidance.

Section 2506—DDT study

Section 2506 requires the Administrator, in cooperation with the Commission of the Food and Drug Administration, to conduct a thorough evaluation of the health effects of DDT and other contamination of fish in Santa Monica Bay, California and in surrounding waters. The evaluation must include an assessment of the level of contamination of edible fish caught in the Bay and surrounding waters, the rate of consumption of contaminated fish from the Bay and surrounding water by residents of Santa Monica and Los Angeles, California, and surrounding communities, and the health risks associated with the consumption of such contaminated fish. The Administrator must complete the evaluation within 6 months after the date of enactment of the bill and report the results of the evaluation to Congress.

TITLE XXVI—PESTICIDE MONITORING IMPROVEMENTS

Section 2601—Short title

Section 2601 provides that title XXVI may be cited as the "Pesticide Monitoring Improvements Act of 1988."

Section 2602—Pesticide monitoring and enforcement information

Section 2602 requires the Secretary of the Health and Human Services and the Commissioner of the Food and Drug Administration to undertake certain new activities designed to improve the capability of the U.S. government to monitor pesticide residue on imported food.

Paragraph (1) of subsection (a) provides for the establishment of computerized data management systems. The Commissioner must evaluate the Administration monitoring program, identify monitoring gaps and likely public health problems resulting from pesticide residues and focus program resources on public health concerns. Such information must be provided to the Environmental Protection Agency.

Paragraph (2) requires that the computerized data management systems be used as soon as practicable to develop the summary of pesticide import volume data required by subsection (c).

Paragraph 3 provides that the requirements of paragraph (1) do not limit the Commissioner's authority to regulate any product covered by the Federal, Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.). The Secretary must comply with applicable regulations governing computer system design and procurement.

Subsection (b) requires that the Commission prepare a summary of the types of imported and domestically produced foods with regard to pesticide residues present on such foods, products sampled, detectible residues, compliance status and violation rates of specific products from specific countries, and resulting administrative action. The Commissioner must also summarize information on the country of origin of food imports and the district of entry for such imports.

Subsection (c) requires that the Commissioner prepare a summary of the volume of each type of imported food products by country of origin and district of entry with a minimum entry value established by the Secretary. The Secretary may rely upon data collected by the U.S. Customs Service implementing this provision. Because the Service currently does not collect comprehensive information on entries with a value lower than $1,000, the Secretary is authorized to exclude such entries from the volume compilation.

Subsection (d) requires that annual summaries referred to subsections (b) and (c) be prepared and made available by the Commission to Federal and State agencies and other interested parties.

Section 2603—Foreign pesticide information

Section 2603 provides for the establishment of cooperative agreements between the United States and the governments of other countries to improve pesticide tolerance compliance.

Subsection (a) requires the Secretary to enter into cooperative agreements with the governments of countries that are major sources of food imported in the United State to assure compliance with pesticide tolerance set under the Federal Food, Drug and Cosmetic Act. Priority attention should be given to developing agreements with those countries that are not covered by existing data sources on commodity-specific pesticide use available to the Secretary on an ongoing basis, such as the Battelle World Agrochemical Databank. The Secretary should also seek data on pesticide use patterns from countries are smaller sources of food imports where necessary to conduct an effective pesticide monitoring program.

Subsection (b) requires that the foreign governments that are parties to the agreements provide current information identifying pesticides used in the production, transportation and storage of foods imported from such countries to the United States. The Secretary should seek, whenever possible, information specific to particular productions areas of the major food-producing countries. Aggregate countrywide data does not reveal important regional variations will assist the Secretary in targeting specific pesticides for analysis.

If the foreign government is unable to provide sufficient information, the Secretary is required to obtain such information. Information obtained by the Secretary must be provided to the Food and Drug Administration and State agencies, except that State agencies

may be provided with information given to Administration confidentially from private sources.

Subsection (c) provides for the Secretary to coordinate with the Department of Agriculture, the Environmental Protection Agency and the Department of State when negotiations with a foreign government to establish a cooperative agreement begin, and to coordinate, as appropriate within the Department.

Subsection (d) requires the Secretary to report to the Committee on Agriculture and Committee on Energy and Commerce of the House of Representatives and the Committee on Agriculture, Nutrition and Forestry and the Committee on Labor and Human Resources of the Senate with regard to the implementation of this section. Such report must be available to appropriate Federal and State agencies and other interested parties.

Section 2604—Pesticide analytical methods

Section 2604 requires that the Secretary, in consultation with the Environmental Protection Agency, to develop a long-range research plan designed to develop improved analytic methods for multiple pesticide residue detection and a review to determine the cost-effectiveness of such methods. The Secretary should focus on methods to detect moderate to high health hazard pesticide residues which are not covered by existing multiresidue methods.

Not later than 240 days after the enactment of this Act, the Secretary must report the specifics of the long-range research plan, the resources needed to carry out such research, recommendations for its implementation and the results of the cost effectiveness review, required by paragraph (2) of this section. Such report must be provided to the committees and other parties named in subsection (d) of section 2603.

TITLE XXVII—CLARIFYING AND TECHNICAL AMENDMENTS

Section 2701—Clarifying amendments

Section 2701 makes clarifying amendments to the Act.

Section 2702—Technical amendments

Section 2702 makes clerical, conforming, and other technical amendments to the Act.

Section 2703—Table of contents amendment

Section 2703 makes amendments to the table of contents of the Act to conform with the amendments to the Act made by the bill.

TITLE XXVIII—EFFECTIVE DATE

Section 2801—Effective date

Section 2801 provides that, except as otherwise provided in the bill, the amendments to the Act made by the bill shall take effect on the expiration of 60 days after the date of enactment of the bill.

Cost Estimate

In accordance with paragraph 11(a) of rule XXVI of the Standing Rules of the Senate, the Committee has included the cost estimate

provided by the Congressional Budget Office. The Committee does not fully concur with this estimate and expects to work with the Congressional Budget Committee to refine it.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, May 13, 1988.

Hon. PATRICK J. LEAHY,
Chairman, Committee on Agriculture,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the attached cost estimate for S. 1516, the Federal Insecticide, Fungicide, and Rodenticide Reform Act of 1988.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

JAMES L. BLUM, *Acting Director.*

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: S. 1516

2. Bill title: Federal Insecticide, Fungicide, and Rodenticide Reform Act of 1988

3. Bill status: As ordered reported by the Senate Committee on Agriculture, Nutrition, and Forestry, April 20, 1988.

4. Bill purpose: S. 1516 would amend the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) by revising the numerous programs and procedures under which the Environmental Protection Agency (EPA) regulates pesticide use, including those related to chemical registration, cancellation and recall. The bill would create a comprehensive program to accelerate the reregistration of substances approved under earlier versions of the act. New groundwater protection measures would be added to the act to regulate pesticide residue levels and improve information management systems. Other amendments would redefine the federal government's obligations to parties affected by regulatory actions and decisions.

For the purposes of carrying out the amended pesticide program, S. 1516 would authorize appropriations for fiscal years 1988 through 1992. Authorized funding levels for abatement, control and enforcement activities would range from $89.6 million in fiscal year 1988 to $115.5 million in 1992. Over this same period, an additional $75 million would be authorized for pesticide research. Also, Title 18 of the bill would authorize the appropriation of matching grants to fund state training and certification programs. Separately, $2.5 million a year would be authorized for groundwater information management under Title 23.

Finally, Title 3 of the bill would impose reregistration and maintenance fees on pesticide registrants to fund the reregistration program.

5. Estimated cost to the Federal Government:

[By fiscal year, in millions of dollars]

	1988	1989	1990	1991	1992
Direct spending:					
Estimated budget authority					
Estimated outlays		−5	−2	1	
Authorizations:					
Estimated authorization level	116	125	129	136	144
Less: existing appropriations	−84				
Additional authorization	32	125	129	136	144
Estimated outlays		95	120	132	142

The costs of this bill fall within budget function 300.

The table does not include any costs that may be incurred as a result of legal actions arising out of the EPA's disclosure of registrant data. Under Title 9, such actions may be brought against the United States if a state improperly uses data obtained from the EPA. In such cases, all state actions shall be deemed to be actions of the federal government and considered a taking of property. As in any situation involving potential costs to satisfy legal claims that may or may not arise in the future, it is not possible to estimate the budgetary impact of this section. However, if successful claims are brought, the cost to the federal government could be significant.

Also, the table does not include possible effects of the bill on indemnity payments or storage and disposal expenses that may be incurred as a result of EPA regulatory actions. These amounts cannot be predicted in advance of final suspension and cancellation decisions.

Basis of estimate: For the purpose of this estimate, it is assumed that S. 1516 will be enacted during fiscal year 1988 and that the full amounts authorized will be appropriated for each fiscal year.

Direct spending: In order to provide additional resources for the reregistration of some 600 active ingredients approved under less stringent versions of FIFRA, Title 3 would impose two new types of fees on pesticide registrants. One is a reregistration fee to be collected in two installments from pesticide manufacturers seeking reregistration. Collections from these fees are expected to be less than $7 million annually, totally between $20 million and $45 million over approximately six years. The second type is an annual maintenance fee to be imposed on each pesticide product registration held by a firm. The maintenance fee schedule is expected to provide approximately $14 million annually over nine years.

Total proceeds from all fees are estimated to be between $150 million and $170 million over the course of the reregistration program.

Upon collection, all fees would be deposited in a revolving fund and would become immediately available to the EPA for reregistration expenses. CBO estimates that fee collections would probably exceed outlays by a small amount in the first two years.

Authorizations: The total cost to the states of carrying out the expanded training and certification/licensing program under Section 23 (as amended) is estimated to be about $20 million a year. In

order to provide the full matching contributions authorized, cooperative agreement grants of approximately $10 million would have to be appropriated for each fiscal year—or nearly triple the $3.5 million provided for this purpose in fiscal year 1988. Other authorizations are specified in the bill.

Outlays for pesticide programs, grants, and data systems development have been estimated on the basis of historical spending patterns for similar activities and information obtained from the EPA and other federal and state authorities. CBO projects that the enactment of S. 1516 late in fiscal year 1988 would result in no additional outlays in this year.

Indemnity payments: Title 13 of the bill would amend those provisions of FIFRA addressing compensation of economic losses incurred by holders of pesticides. Under current law, the EPA is required to make indemnity payments to any person harmed by agency's decision to suspend and cancel the registration of a pesticide. Under the provisions of Title 13, only end users and certain others would be automatically entitled to indemnity payments in the future. Compensation for other claimants such as pesticide registrants would still be permitted subject to case-by-case appropriation.

The impact of this amendment on future federal costs is very uncertain. If pesticide registrations are suspended and cancelled subsequent to the bill's enactment, and if the provisions of Title 13 are successfully invoked to limit indemnity payments, federal outlays may be substantially lower than under current law. (For example, if these provisions had governed federal liability for economic losses incurred and compensated in the past, much of the nearly $27 million spent on indemnity payments to date might have been considered discretionary and might not have been paid.) Future savings are not guaranteed, however. S. 1516 would continue to authorize compensation to all parties affected by suspension and cancellation orders, and if the Congress chooses to appropriate funds for that purpose, no savings would be realized. Moreover, it is possible that claims could be brought against the federal government if such funds are not appropriated.

Disposal and storage costs: Title 16 would specify procedures for the recall of suspended and cancelled pesticides and would distinguish relative federal and private responsibilities for the subsequent storage and disposal of existing inventories. Under current law, the EPA is required to accept and dispose of inventories held by pesticide owners if requested to do so. Upon acceptance of a chemical, the agency is responsible for all of the costs related to its disposal, including interim storage if disposal is delayed.

In contrast, for recalls taking place after enactment of Title 16, the EPA would no longer assume responsibility for the destruction of recalled pesticides and would only be required to pay a portion of the owner's storage costs pending disposal. If pesticide recalls are ordered in the future, federal obligations under the amended act would almost certainly be less burdensome than if governed by current law. Potential savings are substantial. For example, in the case of one cancelled pesticide, Silvex/2,4,5–T, the EPA has already incurred disposal and related costs of about $5 million and will probably spend at least an additional $4 million before disposal has

been completed. The agency has spent approximately $3 million to date on the disposal of a second pesticide, ethylene dibromide (EDB), and may need additional funding of nearly $29 million to complete the project. Disposal costs for Dinoseb, a third substance that is currently undergoing final cancellation proceedings, are expected to be much greater—possibly exceeding $150 million. If the amendments made by Title 16 had been in effect in these three cases, most of these expenses would have been avoided. Furture savings as a result of these provisions are likely, but depend on EPA's future cancellation actions and therefore cannot be reliably projected.

6. Estimated cost to State and local governments: Title 18 would impose new program requirements on states with respect to training and certification responsibilities delegated under cooperative agreements with the EPA. At current appropriation levels of between $2.5 million and $3.5 million a year, the federal contribution to state programs is believed to fall short of the 50 percent currently authorized for existing programs. (While estimates of total state certification and training costs are hard to obtain, some state officials believe that federal cooperative grants of $2.5 million a year in the past have covered only about 30 percent of total costs, implying total program costs of about $8 million a year.) The provisions of Title 18 are expected to increase program costs to nearly $20 million, one-half of which would be recovered through federal matching grants (assuming appropriation of the necessary sums).

Some of the provisions of S. 1516 may increase the pressure on state governments to expand their existing groundwater programs and develop comprehensive pesticide groundwater management plans. For example, many of the regulatory requirements and procedures mandated under Title 23 may become exceedingly difficult for the EPA or states to administer in the absence of state-specific information. If so, states may have little choice but to initiate ambitious groundwater program changes in order to stave off cancellation of a particular pesticide within their borders. The costs of developing and implementing state plans is uncertain. In some states, the necessary plans are already under development, and the incremental costs of conforming an existing program to EPA specification may be small. Moreover, the bill contains no specific requirement that any state must prepare such plans, and states willing to accept possible cancellation of a pesticide in their areas may not fund any program changes. However, for those states that may find themselves faced with an impending cancellation order, the costs of developing and maintaining the necessary programs may be substantial.

7. Estimate comparison: None.

8. Previous CBO estimate: None.

9. Estimate prepared by: Deborah Reis.

10. Estimate approved by: James L. Blum, Assistant Director for Budget Analysis.

Regulatory Impact Evaluation

In accordance with paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee makes the following evaluation

of the regulatory impact that would be incurred in carrying out the Committee bill.

The bill would effect major changes in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), particularly with regard to the pesticide registration and Special Review process, regulation of inert ingredients in pesticide products, protection of ground water, and applicator certification and training.

(a) Description and estimated numbers of individuals and businesses to be regulated

1. Pesticide producers, formulators and dealers.

The pesticide producing indusry of the United States consists of about 30 major manufacturers of active ingredients, along with 100 smaller producers and 3,300 formulators. In a typical year, 200 to 400 new firms register for the first time with the Environmental Protection Agency (EPA) as pesticide manufacturers or formulators.

There are aproximately 29,500 distributors and registered establishments through which pesticides flow in the United States. These various marketing units and establishments are regulated under enforcement programs of FIFRA. Within this group are about 15,000 to 20,000 dealers which would be expected to sell restricted use products.

2. States.

Under FIFRA, the States are EPA's partners in pesticide regulation. All the States would be affected by the certification and training and ground water provisions of the bill.

3. Pesticide applicators/users.

Pesticides are used on a majority of 2 million farms and 75 million households in the United States each year. In addition, there are several million industrial, commercial and governmental users of pesticides in the United States all of which are subject to at least some form of regulation and/or training program under FIFRA.

The amendments affect certified commercial applicators, registered commercial applicators, certified private applicators and supervised private applicators, along with businesses which employ commercial applicators. (Registered commercial applicators and supervised private applicators are two new groups which are affected by the proposed amendments.) Approximately 30,000 commercial applicators will be trained and certified each year, and approximately 200,000 commercial applicators will need to be trained and registered with the States. Approximately 100,000 private applicators will be train and certified each year, and approximately 2,000,000 supervised private applicators will need to receive training.

Under the proposed amendments, there is a new requirement that Federal and State enforcement personnel receive training in the commercial applicator categories for which they are assigned enforcement responsibility. Approximately 25 Federal enforcement

personnel and 200 State enforcement personnel will require training.

(b) Economic impacts on affected individuals and businesses

In general, the economic impacts of FIFRA implementation fall on basic producer registrants, other registrants, primary formulators, users and State authorities. Presented below is a brief discussion of economic impacts of implementation of the proposed amendments.

1. Pesticide Producers

A. Reregistration fees

For basic producers which currently number up to 130 firms, total compliance costs are estimated to be in the range of $160 million industry wide for 1988 under the existing law. There would be significant increases in this baseline cost under the proposed amendments. Basic producer registrants would need to meet new data and other requirements for inert ingredients as well as their active ingredients and formulations. Registrants would incur fees to cover the cost of activities within EPA to reregister active ingredients. There would be additional nominal impacts from additional reporting and recordkeeping requirements in connection with production, distribution, and export of pesticides such as dealing with tolerances and ground water issues. The additional provisions include a requirement for the industry to monitor for ground water residues at some cost and report results of concern to authorities. It is possible that the amendments could increase the cost to basic producers for compliance in the neighborhood of 10–15%, i.e., $16–24 million per year.

The impacts from the proposed amendments on formulators would generally be of limited economic consequences. The major impact of the bill would be the new annual registration maintenance fee of up to $425, adding approximately $14 million in annual compliance costs to help pay for the accelerated reregistration program. A major part of these fees will come from formulators; however, EPA analysis of the registration files indicates that approximately 88% of registrants have ten or fewer product registrations. Thus any impact on the vast majority of formulators is expected to be minimal (less than $4,500 annually). The fee schedule is limited to a maximum of $35,000 annually for any company with over 50 products, and $20,000 for companies with 50 or fewer products.

The legislation also earmarks up to $2 million of the annual fees to enable EPA to more quickly approve routine me-too registrations, which is likely to be a beneficial regulatory impact on many formulators as their products may reach the marketplace more quickly than at present.

After the completion of the accelerated reregistration program as mandated by the legislation, the authority to impose the maintenance fees will expire.

Formulators could be affected by provisions dealing with inert ingredients in instances where the firm had not incurred such costs as a result of also being a producer of the basic active ingredient.

There would not be expected to be more than a 5% increase in costs of compliance for the 3,300 formulators i.e., about $2.5 million per year.

Under the bill dealers supplying restricted use pesticide products would have recordkeeping requirements not required by the present law. It is possible that record requirements could involve one hour of personnel time per week resulting in an annual incremental cost of $500 per firm or about $7.75 million nationwide. There would not appear to be any additional compliance costs for the remaining 14,000 distributors and establishments.

B. Storage, transportation, disposal/indemnification

Changes in the indemnification provisions of the current law will impose new costs on pesticide producers previously borne by the Federal government. The potential regulatory impact on pesticide producers is uncertain since the emergency suspension of a pesticide is a very infrequent occurrence. To date, EPA has only issued four emergency suspension orders which eventually resulted in indemnification. Potential costs on a pesticide producer will also vary greatly depending on the production cycle of the product and a registrant's ability to reformulate or reprocess any suspended stocks.

Assuming that the task (and costs) of recalling and disposing of stocks of a suspended pesticide will be more efficiently conducted by the pesticide producer, future cases requiring the disposal of suspended pesticide stocks will be completed more quickly and inexpensively. Pesticide producers will have had experience in handling and disposing of the product from its manufacture.

The legislation would shift a significant fraction of the costs under the current authority to pesticide manufacturers. Agricultural producers will be indemnified through Federal revenues; manufacturers will be responsible for the costs of transportation and disposal of any suspended and cancelled pesticides. Storage costs for these products will be shared by the manufacturer and EPA. Storage fees are expected to be a relatively small part of total costs of transportation, storage, and disposal of any pesticide product.

Generally, since the eventual costs of any one suspension and cancellation may be high (estimates of the total costs associated with the suspension and cancellation of the pesticide Dinoseb are over $100 million), individual manufacturers are expected to seek insurance coverage or otherwise self-insure to avoid any potential economic catastrophe. Intermediaries in the marketing chain should be minimally impacted as the amendments are designed to leave ultimate responsibility for disposal and most other costs with the pesticide manufacturer. Provisions were also added to minimize any potential impact on retail pesticide dealers.

Potential costs, though large, represent only a small fraction of annual sales for the industry as a whole. Annual domestic sales of pesticides are estimated at $6 billion. The cost to EPA this year for indemnification (which currently includes the costs of transportation, storage, and disposal) is $51 million. Though not a recurring annual expense, it would represent less than 1% of estimated annual domestic sales of pesticides.

2. States.

The cost of the States from the proposed amendments will be approximately $9,000,000. This includes training and certification of applicators, registration of commercial applicators, and prescribing training for applicators and standards for trainers.

3. Pesticide applicators.

The cost to individuals for initial training and certification and registration under the amendments will be approximately $10–20 per person.

4. EPA.

The bill requires EPA to implement a new reregistration program to reregister, over a period of about nine years, pesticides with active ingredients contained in pesticides registered before November 1, 1984. This requirement is both an acceleration of an a substantial change to the current reregistration program. This bill alos provides for reregistration fees to help pay for the cost of the expanded program.

The bill also would have substantial cost impacts on EPA in several other areas including regulation of inert ingredients, and implementation of new cancellation procedures for Special Reviews, and extended applicator certification and training programs, and new ground water response provisions.

(c) Impacts on personal privacy.

None.

(d) Additional paperwork burden likely to result

Base for the current program—4.6 million burden hours.

1. Inert Ingredients.

Slight to moderate increase over current and anticipated program.

2. Public Right to Know; Fact Sheet and Annual Report.

Slight increase: chemical and physical properties of active ingredients are already known and provided to EPA.

3. Public Interim Administrative Review.

No increase over current burden.

4. False and Invalid Data.

No change.

5. Exports.

Could be a substantial increase for registrants and the Federal government to comply with prior informed consent requirements.

6. Data Compensation.

No change.

7. Information Requested.

No change.

8. Ground water.

Could be a substantial increase in burden for registrants, particularly for agricultural use pesticides. Would have increased requirements to identify follow through, monitor, and report on potential ground water contaminants.

9. Health and Safety.

The major burden will be on agricultural chemical users but non-agricultural workers would also be affected. Training and associated record keeping for non-certified applicators could be a major burden and increase. Design and implementation of training requirements will be the major significant burden.

10. Reregistration.

The paperwork burden for the reregistration proposal has two components—a major acceleration of information requirements and substantial increases in the burden caused by changes from the current process.

The filing of data gaps and identification of adverse data for new studies will cause a major short term increase in the paperwork burden. However, this is a burden which would be levied on the industry under the current process although over a much longer time period. Thus the overall burden from these aspects of the proposed program may not differ substantially from. the current program, over the long term.

Several aspects of the proposed program would add to the overall burden. These are:

Registrant identification of missing and inadequate data—moderate increase in overall burden;

Reformatting and summarizing existing data thought to be adequate—moderate increase;

Certification of possession of raw data—slight increase; and

Flagging adverse data for existing studies—slight increase over effort to reformat and summarize.

Each of these tasks adds a slight to moderate increase in the overall burden.

11. Certification and training.

There will be a substantial increase in paperwork for State organizations/agencies responsible for training and certifying pesticide applicators. Such State agencies will be required to train and certify commercial applicators who are not certified, verify training given by private organizations, and reregister and recertify applicators every five years.

The increase in paperwork burden for pesticide dealers will be moderate since in general they will be required to keep records of restricted use pesticides which they sell or distribute. Nine States already have various recordkeeping requirements in place.

CHANGES IN EXISTING LAW

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law made by S. 1516 are shown as follows (existing law proposed to be omitted is enclosed in blacks brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE *REFORM* ACT *OF 1988*

* * * * * * *

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Federal Insecticide, Fungicide, and Rodenticide *Reform Act of 1988*".

[(b) TABLE OF CONTENTS.— * * *]

(b) TABLE OF CONTENTS.—

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(1) Training.
(2) Monitoring.
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(a) In General.
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(3) Congressional committees.
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(d) Expiration.
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(a) Referral.
(b) Notice.
(c) Construction.
Sec. 28. Identification of pests; cooperation with Department of Agriculture's program.
Sec. 29. Annual report.
Sec. 30. Severability.
Sec. 31. Protection of ground water.
(a) Leaching potential.
(1) Criteria.
(2) Information.
(3) Determination of potential to leach.
(4) Determination of necessity of monitoring.
(b) Monitoring.
(1) Requirement for monitoring.
(2) Judicial review.
(c) Notification.
(1) Requirement.
(2) Content of report.
(d) Review for further action.
(e) Registration amendments.
(1) Requirement.
(2) Consultation.
(3) Reasonable likelihood.
(4) Scope of amendments.
(5) Effectiveness amendments.
(6) Procedures.
(f) Site-specific response.
(1) Requirement.
(2) Action by the Administrator.
(3) Judicial review.
(g) Information on pesticides in ground water.
(h) Technical assistance to States.
(i) Special review.
(j) Site specific information.
(1) Availability of information.
(2) Establishment of Council.
(3) Consideration by Administrator.
(k) Effect on other provisions.
Sec. 32. Authorization for appropriations.

SEC. 2. DEFINITIONS.

For purposes of this Act—

(a) * * *

* * * * * * *

(c) ADULTERATED.—The term "Adulterated" applies to any pesticide [if:] *if—*

* * * * * * *

[(e) CERTIFIED APPLICATOR, ETC.—

[(1) CERTIFIED APPLICATOR.—The term "Certified applicator" means any individual who is certified under section 4 as authorized to use or supervise the use of any pesticide which is classified for restricted use. Any applicator who holds or applies registered pesticides, or use dilutions of registered pesticides consistent with section 2(ee) of this Act, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served is not deemed to be a seller or distributor of pesticides under this Act.

[(2) PRIVATE APPLICATOR.—the term "private applicator" means a certified applicator who uses or supervises the use of any pesticide which is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by him or his employer or (if applied without compensation other than trading of personal services between producers of agricultural commodities) on the property of another person.

[(3) COMMERCIAL APPLICATOR.—The term "commercial applicator" means an applicator (whether or not he is a private applicator with respect to some uses) who uses or supervises the use of any pesticide which is classified for restricted use for any purpose or on any property other than as provided by paragraph (2).

[(4) UNDER THE DIRECT SUPERVISION OF A CERTIFIED APPLICATOR.—Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if it is applied by a competent person acting under the instructions and control of a certified applicator who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is applied.]

(e) APPLICATOR.—

(1) COMMERCIAL APPLICATOR.—

(A) Except as provided in subparagraph (B), the term "commercial applicator" means a person (whether or not the person is a private applicator with respect to some uses) who—

(i) uses or supervises the use, for any purpose or on any property, of any pesticide that is classified for restricted use;

(ii) uses or supervises the use of any pesticide (other than a pesticide that the Administrator determines may be applied without the need for training) for hire as the principal part of the business or work of the person; or

(iii) as an employee of a person described in clause (ii), uses or supervises the use of any pesticide.

(B) The term does not include a person who uses or supervises the use of a pesticide as described in paragraph (2).

(2) PRIVATE APPLICATOR.—The term "private applicator" means a person who uses or supervises the use of any pesticide that is classified for restricted use for purposes of producing any agricultural commodity—

(A) on property owned or rented by such person or the employer of such person; or

(B) on other property if applied without compensation (other than trading of personal services between producers of agricultural commodities).

(3) CERTIFIED APPLICATOR.—The term "certified applicator" means a commercial or private applicator who is certified under [*section 4*] *section 11.*

(4) UNDER THE DIRECT SUPERVISION OF A CERTIFIED APPLICATOR.—Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if the pesticide is applied by a person acting under the direct supervision and the instructions and control of a certified applicator who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is used.

* * * * * * *

[(n) INGREDIENT STATEMENT.—The term "ingredient statement" means a statement which contains—

[(1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in the pesticide; and

[(2) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic.]

(n) INGREDIENT STATEMENT.—The term "ingredient statement" means a statement that contains—

(1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in a pesticide;

(2) the name of each inert ingredient in the pesticide that the Administrator determines must appear in the ingredient statement because of the hazard that the Administrator has determined may be posed by the toxicity, use pattern, and concentration level of the inert ingredient in the pesticide;

(3) the name of each ingredient in the pesticide that is present in any other registered pesticide as an active ingredient and, if the Administrator determines that such pesticide ingredient is an inert ingredient in the pesticide, a note stating that the pesticide ingredient is an active ingredient in other pesticide formulations;

(4) of the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic;

(5) any other information concerning the chemical composition or identity of any active ingredient of the pesticide, including information on chemical equivalency, that the Administrator requires to appear in the ingredient statement so that the nature of the active ingredient is accurately represented; and

(6) the name of any inert ingredient for which the Administrator has required additional data under section 3(g)(5) because such ingredient is listed under section 3(g)(1)(A) as appearing to cause a pesticide to meet or exceed a criterion for initiating a public interim administrative review under section 3(c)(8).

* * * * * * *

(p) LABEL AND LABELING.—

(1) LABEL.—The term "label" means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

(2) LABELING.—The term "labeling" means all labels and all other written, printed, or graphic matter—

(A) accompanying the pesticide or device at any time; or

(B) to which reference is made on the label or in literature accompaning the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of [Health, Education, and Welfare], *Health and Human Services* State experiment stations, State agricultural colleges, and other simliar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

(q) MISBRANDED.—

(1) A pesticide is misbranded if—

* * * * * * *

(2) A pesticide is misbranded if—

(A) the label does not bear an ingredient statement on that part of the immediate container (and on the outside container or wrapper of the retial package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions of purchase, except that a pesticide is not misbranded under this subparagraph [if:] *if*—

* * * * * * *

(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through with the required information on the immediate conatiner cannot be clearly read, a lable bearing—

* * * * * * *

(iii) the net weight or measure of the content[: *Provided,* That], *except that* the Administrator may permit reasonable variations; and

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 3(d) of this Act, is adequate to protect health and the environment; [or]

(H) in the case of a pesticide not registered in accordance with section 3 of this Act and intended for export, the

label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the following: "Not Registered for Use in the United States of America"[.]; *or*

(I) in the case of a pesticide intended for export that is substantially similar in composition and use pattern to a pesticide registered under section 3, the label—

(i) is not written in an appropriate language as required by section 17(a)(3)(A); or

(ii) does not contain the same health, safety, and hazard precautions as the pesticide registered under section 3 for uses similar to those to which the exported pesticide may be put.

* * * * * * *

(u) PESTICIDE.—The term "pesticide" means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, [and] (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, *and (3) any substance or mixture of substances intended for a purpose described in subsection (ff)* [: *Provided,* That], *except that* the term "pesticide" shall not include any article [(1)(a)] that is a "new animal drug" within the meaning of section 201(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(w), [or (b)] that has been determined by the Secretary of [Health, Education, and Welfare] *Health and Human Services* not to be a new animal drug by a regulation establishing conditions of use for the article, or [(2) that] *that* is an animal feed within the meaning of section 201(x) of such Act (21 U.S.C. 321(x)) bearing or containing [an article covered by clause (1) of this provision] *a new animal drug.*

* * * * * * *

(ee) TO USE ANY REGISTERED PESTICIDE IN A MANNER INCONSISTENT WITH ITS LABELING.—The term "to use any registered pesticide in a manner inconsistent with its labeling" means to use any registered pesticide in a manner not permitted by the labeling[: *Provided,* That the term], *except that the term* shall not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling *unless the labeling specifically prohibits its deviation from the specified dosage, concentration, or frequency,* (2) applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment, (3) employing any method of application not prohibited by the labeling *unless the labeling specifically states that the product may be applied only by the methods specified on the labeling,* [or] (4) mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited

by the labeling[: *Provided further,* That the term also shall not include], *(5)* any use of a pesticide in conformance with section 5, 18, or 24 of this Act, [or any use] *or (6) any use* of a pesticide in a manner that the Administrator determines to be consistent with the purposes of this Act [: *And provided further,* That after]. *After* March 31, 1979, the term shall not include the use of a pesticide for agricultural or forestry purposes at a dilution less than label dosage unless before or after that date the Administrator issues a regulation or advisory opinion consistent with the study provide for in section 27(b) of the Federal Pesticide Act of 1978, which regulation or advisory opinion specifically requires the use of definite amounts of dilution.

(ff) ANTIMICROBIAL ACTIVE INGREDIENT.—The term "antimicrobial active ingredient" means any active ingredient that is contained only in pesticides that are not registered for any food or feed use and that are—

(1) sanitizers intended to reduce the number of living bacteria or viable virus particles on inanimate surface or in water or air;

(2) bacteriostats intended to inhibit the growth of bacteria in the presence of moisture;

(3) disinfectants intended to destroy or irreversibly inactivate bacteria, fungi, or viruses on surfaces or inanimate objects;

(4) sterilizers intended to destroy viruses and all living bacteria. fungi, and their spores on inanimate surfaces; or

(5) fungicides or fungistats.

(gg) CONTAINER.—The term "container" means any package, can, bottle, bag, barrel, drum, tank, or other containing-device (excluding spray applicator tanks) used to enclose a pesticide or pesticide-related waste.

(hh) COUNTRY OF IMPORT.—The term "country of import" means any foreign country, including the country of ultimate destination and all transit countries, to which a pesticide, device, or active ingredient is exported from the United States.

(ii) DRINKING WATER WELL.—The term "drinking water well" means a well or spring currently supplying water for human consumption.

(jj) EXPORTER.—The term "exporter" means any person who arranges to transport, or who transports, any pesticide, device, or active ingredient to any country of import.

(kk) GROUND WATER.—The term "ground water" means water below the land surface in a zone of saturation.

(ll) GROUND WATER RESIDUE GUIDANCE LEVEL.—The term "ground water residue guidance level" means a ground water residue guidance level established under section 1429 of the Public Health Service Act (42 U.S.C. 300h–8).

(mm) GROUND WATER SAMPLING POINT.—The term "ground water sampling point" means a public or community water supply, a private water supply, a spring, or a monitoring well or other ground water source, if the well or source is reasonably designed and of adequate depth to permit the collection of representative ground water samples.

(nn) OUTSTANDING DATA REQUIREMENT.—

(1) IN GENERAL.—The term "outstanding data requirement" means a requirement for any study, information, or data that is

necessary to make a determination under section 3(c)(5) and which study, information, or data—

(A) has not been submitted to the Administrator; or

(B) if submitted to the Administrator, the Adminstrator has determined must be resubmitted because it is not valid, complete, or adequate to make a determination under section 3(c)(5) and the regulations and guidelines issued under such section, as determined by the Adminstrator.

(2) FACTORS.—In making a determination under paragraph (1)(B) respecting a study, the Administrator shall examine, at a minimum, relevant protocols, documentation of the conduct and analysis of the study, and the results of the study to determine whether the study and the results of the study fulfill the data requirement for which the study was submitted to the Administrator.

(oo) PESTICIDE TESTING FACILITY.—The term "pesticide testing facility" means any person that conducts any test, study, survey, or investigation of the properties, effects, or behavior of any pesticide (or any ingredient, metabolite, or degradation product thereof) on its own behalf or on behalf of any registrant, applicant for registration, or other person who sells or distributes the pesticide (or contemplates selling or distributing the pesticide). The term does not include any person solely on account of the participation of such person as a cooperator in field testing of a pesticide in compliance with an experimental use permit issued under section 5.

(pp) POTENTIAL SOURCE OF DRINKING WATER.—The term "potential source of drinking water" means an aquifer or portion of an aquifer system that may supply a drinking water well. Any determination as to whether an aquifer or a portion of an acquifer is a potential source of drinking water shall include—

(1) whether there is water of sufficient quantity and quality to supply a drinking water well;

(2) hydrogeological considerations and depth to drinking water; and

(3) geographic considerations including any State criteria or guidelines established under section 1428 of the Public Health Service Act (42 U.S.C. 300h-7) or other State authority.

(qq) RELIABLE ANALYTICAL DATA.—The term "reliable analytical data" means scientific information that verifies the presence of a pesticide in a ground water sample and that is of a reliable scientific quality according to generally recognized standards and good laboratory practices for sampling and analysis of pesticides in ground water.

(rr) TO DISTRIBUTE OR SELL.—The term "to distribute or sell" means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver. The term does not include the holding or application of registered pesticides or use dilutions thereof by any applicator who provides a service of controlling pests without delivering any unapplied pesticide to any person so served.

* * * * * * *

SEC. 3. REGISTRATION OF PESTICIDES.

[(a) REQUIREMENT.—Except as otherwise provided by this Act, no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator.]

(a) REQUIREMENT OF REGISTRATION.—Except as provided by this Act, no person in any State may distribute or sell to any person any pesticide that is not registered under this Act. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this Act and that is not the subject of an experimental use permit under section 5 or an emergency exemption under section 18.

* * * * * * *

(c) PROCEDURE FOR REGISTRATION.—

(1) STATEMENT REQUIRED.—Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

(A) * * *

* * * * * * *

(D) except as otherwise provided in [subsection (c)(2)(D) of this section], *paragraph 2 (D)* if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) With respect to pesticides containing active ingredients that are initially registered under this Act after the date of enactment of the Federal Pesticide Act of 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide: [*Provided*, That such]. *Such* permission shall not be required in the case of defensive data[;].

(ii) [except as], *Except as* otherwise provided in [subparagraph (D)(i) of this pargraph] *clause (i)*, with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, [or for reregisration,] *for reregistration, or to support the safety of an inert ingredient* the Administrator

may, without the permission of the original data submitter, consider any such item of data in support of an application *or in support of the safety of an inert ingredient* by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determinations, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this Act. If the Administrator determines that an applicant has failed to participte in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which

the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation[;].

(iii)(I) In the case of a pesticide the term of the patent for which has expired, the terms and amount of compensation, for data that was submitted for such pesticide, to be paid by a person who intends to file an application for registration of a pesticide that cites such data may be fixed before the submission of such application by arbitration under clause (ii) initated by such person.

(II) The arbitration shall be binding on the original data submitter and shall be binding on such person after the the date the application of such person is submitted.

(III) No official or court of the United States shall have power or jurisdiction to review any such finding or determination of the arbitrator, except for fraud, misrepresenatation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint, with supporting affidavits, attesting to specific instances of such fraud, misrepresentation, or other misconduct.

(IV) Each party to the first arbitration under this clause to determine the terms and amount of compensation for the use of particular data shall share equally in the payment of the fees and expenses of the arbitrators and shall each pay its own attorney's fees.

(V) In all subsequent arbitrations under this clause to determine the terms and amount of compensation for the use of such data, the party to such subsequent arbitration who seeks to cite the data of the original data submitter shall pay the fees and expenses of the arbitrators and the attorney's fees of the original data submitter.

(IV) Clause (ii) shall apply to arbitrations under this clause, except as otherwise provided in this clause.

[(iii)] *(iv)* [after expiration] *After expiration* of any period of exclusive use and any period for which compensation is required for the use of an item of data under [subparagraphs (D)(i) and (D)(ii) of this paragraph], *clauses (i), (ii), and (iii),* the Administrator may consider such item of data in support of an application by any other applicant without the permission

of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data [;].

* * * * * * *

[(2)(A) DATA IN SUPPORT OF REGISTRATION.—The]
(2) DATA IN SUPPORT OF REGISTRATION.—

(A) The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter he requires any additional kind of information under subparagraph (B) of this paragraph *(including information concerning an inert ingredient in a pesticide)* he shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, and the level and degree of potential exposure of man and the environment to the pesticide. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 10, within 30 days after the Administrator registers a pesticide under this Act he shall make available to the public the data called for in the registration statement together with such other scientific information as he deems relevant to his decision.

[(B) ADDITIONAL DATA TO SUPPORT EXISTING REGISTRATION.—

[(i) If] *(B)(i) If* the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.

[(ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within ninety days after notification. Any registrant who agrees to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration.]

(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide or the existing registrations of a group of pesticides, the Administrator shall notify the

registrant of each pesticide to which the determination relates and provide a list of such registrants to any person.

(ii)(I) Each registrant of such a pesticide shall provide evidance within 90 days after receipt of notification that the registrant is taking appropriate steps to secure and submit the additional data that are required.

(II) Two or more registrants may agree to develop jointly, or to share in the cost of development of, such data. Any registrant who enters into such as agreement, or who offers to agree to share in the cost of development of such data, shall be entitled to examine such data and rely on such data to maintain or obtain registrations under this Act on under the law of any State. An offer to enter into such an agreement may be accepted at any time and may not be withdrawn without the consent of the person to whom the offer was made.

(iii) [If, at the end of sixty days after advising the Administrator of their agreement to develop jointly, or share in the cost of developing data, the registrants have not further agreed on the terms of the data development arrangement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service.] *If at the end of 60 days after two or more registrants have entered into an agreement under clause (ii) the registrants have not further agreed on the terms of the data development of costsharing agreement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings to fix such terms by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by the Service.* The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator.

(iv) Notwithstanding any other provision of this Act, if the Administrator determines that a registrant, within the time required by the Administrator, has

failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and efective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that seved as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 6(d) of this Act[*: Provided,* That the]. *The* only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provision of this Act, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

(v) Any data submitted under this subparagraph shall be subject to the provisions of subsection [(c)(1)(D) of this section] *paragraph (1)(D).* Whenever such data are submitted jointly by two or more registrants, an agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation matters for the joint submitters of such data.

(vi) Whenever tests of a type specified in the guidelines promulgated under subparagraph (A) or this subparagraph are requested by more than one Federal or State agency to support a pesticide registration, such tests with respect to such aspects as test protocols, time-

tables, and standards of review, shall be coordinated and synchronized among the agencies so as to avoid unnecessary repetition and redundancy. Within 1 year after the date of enactment of this clause, the Administrator shall develop, by rule, and implement procedures for such coordination and synchronization so as to result in identical test methodologies acceptable to all the agencies. In the case of an unresolved dispute, the agencies shall submit the facts to the Scientific Advisory Panel established under section 25(d) for a recommendation that will be considered by the agencies for a final determination relative to coordination and synchronization. Nothing in this clause shall be interpreted as adversely affecting the authority of States to test, regulate, or otherwise control the use of a pesticide.

(C) [SIMPLIFIED PROCEDURES.—]Within nine months after the date of enactment of this subparagraph, the Administrator shall, by regulation, prescribe simplified procedures for the registration of pesticides, which shall include the provisions of subparagraphs (D) of this paragraph.

[(D) EXEMPTION.—No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into an end-use product shall be required to—

[(i) submit or cite data pertaining to the safety of such purchased product; or

[(ii) offer to pay reasonable compensation otherwise required by pararaph (1)(D) of this subsection for the use of any such data.]

(D)(i) No applicant for registration or amended registration of a pesticide who proposes to purchase a registered pesticide from another producer to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to—

(I) submit or cite data pertaining to such purchased pesticide; or

(II) offer to pay reasonable compensation otherwise required by paragraph (1)(D) for the use of any such data.

(ii) No applicant for registration or amended registration of a pesticide who proposes to purchase an inert ingredient from another person to formulate the pesticide shall be required to offer to pay reasonable compensation otherwise required by paragraph (1)(D) for a study concerning such ingredient if any portion of the cost of the study will be or could be included in the price of the purchased ingredient.

(3) TIME FOR ACTING WITH RESPECT TO [APPLICATION.—The Administrator] *APPLICATION.—*

(A) The Administrator shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide in accordance with paragraph (5), or notify the applicant of his determination that it does not comply with the provisions of the Act in accordance with paragraph (6).

(B)(i) The Administrator shall, as expeditiously as possible, review and act on any application received by the Administrator that—

(I) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; or

(II) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data.

(ii) In expediting the review of an application for an action described in clause (i), the Administrator shall—

(I) within 45 days after receiving the application, notify the registrant whether or not the application is complete and, if the application is found to be incomplete, reject the application;

(II) within 90 days after receiving a complete application, notify the registrant if the application has been granted or denied; and

(III) if the application is denied, notify the registrant in writing of the specific reasons for the denial of the application.

(4) NOTICE OF APPLICATION.—The Administrator shall publish in the Federal Register, [promptly] *not later than 30 days* after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. [The notice] *Except as provided in paragraph (9), the notice* shall provide for a period of [30] *60* days in which any Federal agency or any other interested person may comment.

(5) APPROVAL OF REGISTRATION.—The * * *

* * * * * * *

[(6) DENIAL OF REGISTRATION.—If the Administrator determines that the requirements of paragraph (5) for registration are not satisfied, he shall notify the applicant for registration of his determination and of his reasons (including the factual basis) therefor, and that, unless the applicant corrects the conditions and notifies the Administrator thereof during the 30-day period beginning with the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide. Whenever the Administrator refuses to register a pesticide, he shall notify the applicant of his decision and of his reasons (including the factual basis) therefor. The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor. Upon such notification, the applicant for registration or other

interested person with the concurrence of the applicant shall have the same remedies as provided for in section 6.]

(6) DENIAL OF REGISTRATION.—

(A) If the Administrator determines that the requirements of paragraph (5) for registration are not satisfied, the Administrator shall notify the applicant or registration—

(i) of the determination and of the reasons therefor (including the factual basis); and

(ii) unless the applicant corrects the conditions and notifies the Administrator thereof during the 30-day period beginning with the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide.

(B) Whenever the Administrator refuses to register a pesticide, the Administrator shall notify the applicant of the decision of the Administrator and the reasons therefor (including the factual basis). The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor.

(C)(i) On such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 6, except as otherwise provided in this subparagraph.

(ii) A request for a hearing under section 6 shall be made within 30 days after the receipt of such notification.

(iii) The Administrator may issue regulations governing the right to a hearing under section 6 with regard to the denial of any application for the registration of a pesticide containing an ingredient that was canceled under section 6. Under such regulations, due weight shall be given to the desirability of finality of prior proceedings and determinations and the extent that the applicant had an opportunity to participate in earlier proceedings.

(7) REGISTRATION UNDER SPECIAL CIRCUMSTANCES.—Notwithstanding the provisions of [subsection (c)(5) of this section] *paragraph 5—*

(A) The Administrator may conditionally register or amend the registration of a pesticide if the Administrator determines that (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. An applicant seeking conditional registration or amended registration under this subparagraph shall [submit] *submit or cite* such data as would be required to obtain registration of a similar pesticide under [subsection (c)(5) of this section] *Paragraph 5*[: *Provided,* That, if]. *If* the applicant is unable to [submit] *submit or cite* an item of data because it has not yet been generated, the Administrator may register or amend the registration of the pesticide

under such conditions as will require the [submission] *submission or citation* of such data not later than the time such data be required to be [submitted] *submitted or cited* with respect to similar pesticides already registered under this Act.

[(B) The Administrator may conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. Notwithstanding the foregoing provisions of this subparagraph, no registration of pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure enumerated in regulations issued under this Act, and during the pendency of any risk-benefit evaluation initiated by such notice, if (I) the additional use of such pesticide involves a major food or feed crop, or (II) the additional use of such pesticide involves a minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, there is available an effective alternative pesticide that does not meet or exceed such risk criteria. An applicant seeking amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under [subsection (c)(5) of this section] *Paragraph 5*: *Provided,* That, if the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated, the Administrator may amend the registration under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this Act.

[(C) The Administrator may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this Act, and on such other conditions as the Administrator may prescribe: *Provided,* That a conditional registration under this subparagraph shall be granted only if the Administrator determines that use of the pesticide during such period

will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.]

(B)(i) The Administrator may conditionally amend the registration of a pesticide under this subparagraph to permit additional uses of such pesticide notwithstanding the fact that data concerning the pesticide may be insuffient to support an unconditional amendment, if the Administrator determines that—

(I) the applicant has submitted or cited additional data that the Administrator may require solely for the proposed additional use;

(II) amending the registration in the manner proposed by the applicant would not materially increase the risk of any unreasonable adverse effect on the environment; and

(III) the additional use is in the public interest.

(ii)(I) Except as provided in subclause (II), if the Administrator has issued a notice stating that a pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure and specified in regulations issued under paragraph (8), no registration of the pesticide may be amended under clause (i) to add any food or feed use during the pendency of any evaluation by the Administrator initiated by such notice.

(II) If the Administrator has issued a notice stating that a pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure and specified in regulations issued under paragraph (8), the Administrator may amend the registration of the pesticide under clause (i) to add a minor food or feed use if the Administrator determines, with the concurrence of the Secretary of Agriculture, that there is not available an effective alternative pesticide that does not meet or exceed such risk criteria.

(iii) An applicant seeking an amended registration of a pesticide under this subparagraph shall submit or cite to the Administrator such data as would be required to obtain a registration of a similar pesticide under paragraph (5). Except as provided in clause (iv), if the applicant is unable to submit or cite an item of such data because it has not yet been generated, the Administrator may amend the registration of the pesticide under such conditions as will require the submission or citation of such data not later than the time such data are requried to be submitted for the maintenance of a registrtion of the similar pesticide under this section.

(iv) If data concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, or teratogenicity are required to support the registration of a pesticide and if a period reasonably sufficient for the generation and submission of such data has elapsed since the Administrator first imposed the data requirement, a conditional amendment to permit an additional use of the pesticide for other

than a minor use shall not be granted under clause (i) unless such data have been submitted.

(C)(i) The Administrator may conditionally register a pesticide under this subparagraph containing an active ingredient not contained in any registered pesticide for a period reasonably sufficient for generation and submission of requred data that have not been submitted because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement—

(I) on the conditions that by the end of such period the Administrator receives such data and that the data that the Administrator receives do not meet or exceed risk criteria enumerated in regulations issued under paragraph (8); and

(II) on such other conditions as the Administrator may prescribe.

(ii) A conditional registration under this subparagraph shall be granted only if the Administrator determines that—

(I) use of the pesticide during the period referred to in clause (i) will not cause any unreasonable adverse effect on the environment; and

(II) use of the pesticide is in the public interest.

(iii) The Administrator shall not conditionally register a pesticide under this subparagraph if—

(I) data concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, or teratogenicity would be required for registration of such a pesticide under paragraph (5);

(II) a period reasonably sufficient for generation of such data has elapsed since the Administrator first imposed the data requirement; and

(III) such data have not been submitted to the Administrator.

[(8) INTERIM ADMINISTRATIVE REVIEW.—Notwithstanding any other provision of this Act, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide, required under this Act, unless such interim administrtive process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment. Notice of the definition of the terms "validated test" and "other significant evidence" as used herein shall be published by the Administrator in the Federal Register.]

(8) PUBLIC INTERIM ADMINISTRATIVE REVIEW.—

(A) A public interim administrative review process to determine whether the use of a pesticide (including a category of pesticides) may cause unreasonable adverse effects onthe environment shall be conducted in accordance with this paragraph.

(B)(i) Criteria for initiating a public interim administrative review of a pesticide shall be set forth in regulations published by the Administrator.

(ii) Such criteria shall be established on the basis of levels of risk and may include consideration of currently available exposure data.

(iii) Absence of exposure data shall not delay or preclude initiation of a public interim administrative review. The Administrator may decline to initiate a public interim administrative review solely on the basis of exposure only if adequate data on all relevant means of exposure have been considered.

(C) The Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of a pesticide or any of its uses before initiating a formal action to cancel, suspend, or deny the registration of such pesticide required under this Act unless such public interim administrative review process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment.

(D)(i) On receipt of information respecting a pesticide demonstrating that the criteria for initiating a public interim administrative review established under subparagraph (B) have been met, the Administrator shall immediately notify all registrants of such pesticide and provide the registrants with appropriate information and an explanation of the manner in which the criteria have been met.

(ii) Not later than 30 days after receipt of a notice provided under clause (i), a registrant may respond to such notice.

(iii) Not later than 60 days after the Administrator provides a notice under clause (i) concerning a pesticide, the Administrator shall determine whether a public interim administrative review of the pesticide shall be initiated.

(E) If the Administrator intends to initiate a public interim administrative review of a pesticide that is registered for agricultural uses, the Administrator shall notify the Secretary of Agriculture of the intention to initiate such review and the reasons therefor.

(F)(i) Any public interim administrative review proceeding shall be initiated and conducted in accordance with regulations published by the Administrator. Such regulations shall provide that a public interim administrative review shall include—

(I) a notice of initiation of the public interim administrative review and opportunity for public comment on such notice;

(II) a notice of a preliminary determination and opportunity for public comment on such notice; and

(III) a notice of a final determination,

except that such regulations may authorize the Administrator to combine or forgo any such notice.

(ii) Any proposed determination of the Administrator shall be submitted to the Scientific Advisory Panel estab-

lished under section 25(d) at its next scheduled meeting for comment solely on relevant scientific issues. Any member of the public may submit comments to the Scientific Advisory Panel concerning such issues.

(iii)(I) The notice of the initiation of a public interim administrative review or the notice of a preliminary determination shall state the basis for such review or determination and include a request for any additional data needed and a bibliography of all scientific data and studies and expert analyses concerning the risks or benefits of the pesticide that are under review.

(II) Information in the bibliography shall be made available to the public consistent with section 10. The Administrator shall determine, to the extent feasible, before the initiation of the public interim administrative review which data in the bibliography may be disclosed to the public under section 10.

(III) If the Administrator receives additional data concerning such risks or benefits, the Administrator, within 30 days after receiving the additional data, shall revise the bibliography to reflect such data and make the revised bibliography available to the public.

(iv)(I) Not later than 90 days after the publication of a notice of the initiation of a public interim administrative review or a notice of a preliminary determination, comments may be submitted on such review or determination. Any person who submits comments shall disclose to the Administrator all scientific data and studies and expert analyses in the possession of such person concerning the risks or benefits of the uses of the pesticide that are under review that were not included in the bibliography included in such notice.

(II) If such person receives additional scientific data or studies or expert analyses of such data or studies that were not included in such bibliography, the person shall disclose such scientific data, studies, and expert analysis to the Administrator within 30 days after receipt.

(v) Not later than 18 months after the initiation of a review, the Administrator shall decide which regulatory action (if any) to take regarding the pesticide that is the subject of the review and shall publish the decision.

(vi) The time limits specified in this subparagraph may not be extended, except in exceptional circumstances in which—

(I) additional data critical to a fair and accurate determination of risks posed by the pesticide subject to review are required;

(II) the extension is for a period limited to the time required to obtain such data on an expedited basis and in no event to exceed 1 year; and

(III) the Administrator acted to obtain the additional data at the time the public interim administrative review was initiated unless the Administrator could

not have reasonably known of the need for such data at such time.

(G) Any person may seek judicial reveiw under section 16(a) of the failure of the Administrator to act within the time period prescribed under this paragraph.

(9) PREREGISTRATION ACCESS TO DATA.—

(A) If an application for—

(i) a registration of a pesticide containing a new active ingredient; or

(ii) a registration of a pesticide to authorize the initial food use of a pesticide active ingredient,

is submitted to the Administrator, the Administrator, before acting on such application, shall provide, in accordance with this pargraph, public access to health, safety, and environmental data that are submitted or cited in support of such application.

(B) To obtain access to the data referred to in subparagraph (A), a person shall send by certified mail—

(i) not later than 30 days after the publication under paragraph (4) of a notice of the application referred to in subparagraph (A); and

(ii) simultaneously to the Administrator and to the applicant for the registration of the pesticide,

a request for such access and the affirmation required by subparagraph (D).

(C)(i) Unless within 15 days after the receipt by the Administrator of a request for access to such data and of an affirmation complying with subparagraph (D) the applicant submits to the Administrator an objection to the request asserting that the affirmation is inaccurate and the reasons for the objection, the Administrator shall grant the request. If an objection to a request is submitted to the Administrator within such 15-day period, the Administrator shall determine whether to grant the request within 5 days after the receipt of the objection. If the Administrator determines to grant the request, access shall not be permitted until 5 days after the applicant making the objection has been notified that access has been granted.

(ii) If access to data is denied under clause (i), comments on the application for which such data were submitted or cited shall be filed within 60 days after the decision of the Administrator denying access.

(D)(i) Data referred to in subparagraph (A) may be made available only to a person who provides an affirmation (and such supporting evidence as the Administrator considers necessary) containing the information prescribed by clause (ii).

(ii) The affirmation required under clause (i) shall—

(I) state that the person is not engaged in, and is neither employed by nor acting (directly or indirectly) on behalf of any other person or affiliate thereof engaged in, the production, sale, or distribution of a pesticide;

(II) identify any business, employer, or other person, if any, on whose behalf the person is requesting access to the data; and

(III) state that the person will not intentionally or recklessly violate this paragraph.

(iii) For purposes of clause (ii), an affiliate of a person is a person who directly or indirectly, through one or more intermediates, controls or is controlled by or is under common control with the other person.

(iv) Section 1001 of title 18, United States Code, shall apply to an affirmation made under this subparagraph.

(E)(i) Data supporting an application may be made available under subparagraph (A) to a person only for the purpose of permitting the person to comment to the Administrator on such application. Such comments may reasonably quote data submitted to the Administrator. No person, including the Administrator, may make such comments public before the decision of the Administrator on the application for the registration of the pesticide for which such data were submitted or after such decision if the application for registration is denied.

(ii) Except as provided in clause (iii), a person who obtains data under subparagraph (A) (directly or indirectly) may not–

(I) publish, copy, or transfer the data to any other person to obtain approval to sell, manufacture, or distribute a pesticide anywhere in the world; or

(II) use the data for any purpose in any court or agency of the United States or any State or political subdivision thereof before the decision of the Administrator on the application for the registration of the pesticide for which such data were submitted or after such decision if the application for registration is denied.

(iii) Such data and comments may be disclosed consistent with section 10 after registration of the pesticide for which such data were submitted.

(F)(i) Data made available under this paragraph may be examined at an office of the Environmental Protection Agency or an appropriate State agency under the conditions prescribed by this paragraph and may not be removed from such office.

(ii) The Administrator shall maintain a record of the persons who inspect data. A copy of such record shall be sent to the data submitter on request.

(G) Once access to data respecting an application is granted, the data may be examined and notes may be taken for use in developing comments on the application. Such comments on the application shall be filed within 60 days after the decision of the Administrator granting access, unless the comment period is extended by the Administrator for an additional 30 days for good cause.

(d) CLASSIFICATION OF PESTICIDES.—

(1) CLASSIFICATION FOR GENERAL USE, RESTRICTED USE, OR BOTH.—

(A) As a part of the registration of a pesticide the Administrator shall classify it as being for general use or for restricted use[, provided that if]. *If* the Administrator determines that some of the uses for which the pesticide is registered should be for general use and that other uses for which it is registered should be for restricted use, he shall classify it for both general use and restricted use. Pesticide uses may be classified by regulation [on the initial classification] and registered pesticides may be classified prior to reregistration. If some of the uses of the pesticide are classified for general use and other uses are classified for restricted use, the directions relating to its general uses shall be clearly separated and distinguished from those directions relating to its restricted uses[: *Provided, however,* That the]. *The* Administrator may require that its packaging and labeling for restricted uses shall be clearly distinguishable from its packaging and labeling for general uses.

(B) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment, he will classify the pesticide, or the particular use or uses of the pesticide to which the determination applies, for general use.

(C) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, he shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted use[:].

[(i) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that the acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, the pesticide shall be applied for any use to which the restricted classification applies only by or under the direct supervision of a certified applicator.]

[(ii)] If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certi-

fied applicator, or subject to such other restrictions as the Administrator may provide by regulation. [Any such regulation shall be reviewable in the appropriate court of appeals upon petition of a person adversely affected filed within 60 days of the publication of the regulation in final form.] *Any such regulation shall be reviewable in accordance with section 16(e).*

* * * * * * *

(f) MISCELLANEOUS.—

(1) EFFECT OF CHANGE OF LABELING OR FORMULATION.—If the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change if the Administrator determines that the change will not violate any provision of this Act.

(2) REGISTRATION NOT A DEFENSE.—In no event shall registration of an article be construed as a defense for the commission of any offense under this Act[: *Provided,*That as]. *As* long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the Act.

(3) AUTHORITY TO CONSULT OTHER FEDERAL AGENCIES.—In connection with consideration of any registration or application for registration under this section, the Administrator may consult with any other Federal agency.

* * * * * * * *

(4) IN-PLANT APPLICATION OF WOOD PRESERVING PESTICIDES.—In regulating the in-plant application of a wood preserving pesticide under this Act, the Administrator shall, by label requirement, assure that excess quantities of the pesticide that are collected and contained to be reapplied by the same user in the wood preserving process shall be regulated as a pesticide.

[(g) REREGISTRATION OF PESTICIDES.—The Administrator shall accomplish the reregistration of all pesticides in the most expeditious manner practicable: *Provided,* That, to the extent appropriate, any pesticide that results in a postharvest residue in or on food or feed crops shall be given priority in the reregistration process.]

(g) PRIORITY LIST AND DATA REQUIREMENTS FOR INERT INGREDIENTS.—

(1) ESTABLISHMENT OF LIST.—

"(A) Subject to paragraph (4), the Administrator shall establish a priority list of inert ingredients consisting of—

(i) inert ingredients that appear to cause a pesticide to meet or exceed a criterion for initiating a public interim administrative review under subsection (c)(8);

(ii) inert ingredients—

(I) for which additional data are reasonably necessary to assess the risk that the inert ingredient may result in a pesticide causing an unreasonable adverse effect on the environment;

(II) that are similar in molecular structure to a chemical that is oncogenic, mutagenic, or terato-

genic or causes another similarly significant adverse effect; and

(III) that have significant use in pesticides or to which there is significant exposure from pesticides; and

(iii) inert ingredients for which additional data are reasonably necessary to assess the risk that the inert ingredient may result in a pesticide causing an unreasonable adverse effect on the environment and to which there is significant exposure from pesticides.

(B) In establishing the priority list, the Administrator may take into account—

(i) the differences in concept, usage, and environmental risk between various classes of pesticides; and

(ii) data for evaluating such risk between agricultural and nonagricultural pesticides.

(2) PUBLICATION OF LIST.—Not later than 90 days after the effective date of this subsection, the Administrator shall publish the priority list required under paragraph (l). The Administrator shall publish revisions to such list at least annually.

(3) JUDICIAL REVIEW.—The priority list under paragraph (1), the inclusion or exclusion of an ingredient on or from the priority list, and any revision of the priority list shall not be subject to judicial review.

(4) NUMBER OF INGREDIENTS.—The priority list under paragraph (l) shall consist of not less than 50 inert ingredients unless the Administrator determines that there is not a sufficient number of inert ingredients meeting the requirements for listing under paragraph (l) to reach such minimum number. Such list may not exceed 75 inert ingredients.

(5) ADDITIONAL DATA.—

(A)(i) The Administrator shall determine whether additional data are required for an inert ingredient in a registered pesticide not later than 1 year after the inert ingredient is placed on the priority list under paragraph (l).

(ii) The Administrator shall require submission of such data from each registrant of such pesticide under this Act or from manufacturers and processors of the inert ingredient under the Toxic Substances Control Act (15 U.S.C. 2601 et seq.).

(iii) Such data shall be submitted within a reasonable time but not later than 4 years after the date of the request. The Administrator may extend the period for the submission of data by not more than 2 years if extraordinary circumstances beyond the control of the registrant or producer prevent the submission of the necessary data.

(B) Data requirements imposed under subparagraph (A) or a decision not to require data for an inert ingredient shall be subject to judicial review under section 16(b).

(6) EVALUATION.—Within 1 year after the receipt of additional data under paragraph (5) for an inert ingredient, the Administator shall evaluate the data and take such steps as are appropriate to prevent unreasonable adverse effects on the environment caused by pesticides containing such inert ingredient.

Under exceptional circumstances, the Administrator may extend the period for evaluation by not more than 1 year.

(7) CONSTRUCTION.—This subsection shall not be construed to affect the authority of the Administrator—

(A) to regulate under this Act impurities, contaminants, degradants, or other ingredients of pesticides that have not been deliberately added to the pesticides;

(B) to regulate under this Act any deliberately added inert ingredient that has not previously been used in a pesticide or any significant new use in a pesticide of a deliberately added inert ingredient;

(C) to require the submission of short term, environmental fate, or residue studies for deliberately added inert ingredients; or

(D) to require the submission of revised formula statements under subsection (c)(2)(B).

(h) ANTIMICROBIAL STANDARDS.—

(1) STANDARDS.—The Administrator shall—

(A) establish efficacy standards for antimicrobial control agents (including disinfectants) used to control pest microorganisms that pose a threat to human health, including standards for disinfectants used in hospitals and other health care facilities;

(B) conduct, or require to be conducted, representative monitoring (including testing) of the compliance of the agents with the standards; and

(C) implement an enforcement program under which the agents must comply with the standards or be prohibited from sale or distribution as an antimicrobial active agent.

(2) DEFINITION.—As used in paragraph (1), the term "efficacy" means the capacity of an antimicrobial control agent (including a disinfectant) to produce the desired effect or the effectiveness of such an agent.

(i) NEUROTOXICOLOGICAL AND BEHAVIORAL EFFECTS TESTING.—The Administrator shall—

(1) develop methods for testing to accurately detect neurotoxicological and behavioral effects of pesticides, and their ingredients; and

(2) as such methods are developed, requrie to the extent appropriate and necessary, that data from such testing be submitted by persons seeking to obtain or maintain pesticide registrations.

SEC. [3A]4. REREGISTRATION OF REGISTERED PESTICIDES.

(a) GENERAL RULE.—The Administrator shall reregister, in accordance with this section, each registered pesticide containing any active ingredient contained in any pesticide first registered before November 1, 1984, except for any pesticide as to which the Administrator has determined, after November 1, 1984, and before the effective date of this section, that—

(1) there are no outstanding data requirements; and

(2) the requirements of section 3(c)(5) have been satisfied.

(b) SPECIAL AUTHORITIES OF ADMINISTRATOR.—

(1) GUIDELINES.—

(A) Not later than 1 year after the effective date of this section, the Administrator, by order, shall issue guidelines to be followed by registrants in accordance with subsection (f)(1) in—

(i) summarizing studies;

(ii) reformatting studies;

(iii) identifying adverse information; and

(iv) identifying studies that have been submitted previously that may not meet the requirements of section 3 or regulations issued under such section.

(B) Guidelines issued under this paragraph shall not be subject to judicial review.

(2) MONITORING.—The Administator shall monitor the progress fo registrants in acquiring and submitting the data required under this section.

(3) SUSPENSIONS AND PENALTIES.—

(A) The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 3(c)(2)(B)(iv) if—

(i) the Administrator determines that progress is insufficient to ensure the submission of the data required for such pesticide under a commitment made under subsection (e)(3)(B) or (f)(1)(H) within the time period prescribed by subsection (e)(4)(B) or (f)(2)(B) or the registrant has not submitted such data to the Administrator within such time period;

(ii) the Administrator determines that tests necessary to fill an outstanding data requirement for such pesticide have not been initiated within 1 year after the issuance of a notice under subsection (g)(1)(B);

(iii) the Administrator determines that progress is insufficient to ensure submission of the data referred to in clause (ii) within the time period prescribed by section (g)(2)(B) or the required data have not been submitted to the Administrator within such time period; or

(iv) a registrant fails to comply with clause (ii) or (iii) of section 3(c)(2)(B).

(B) A registrant who submits a certification under subsection (f)(1)(G) that is false shall be considered to have violated this Act and shall be subject to the penalties prescribed by section 14.

(c) REREGISTRATION PHASES.—Reregistrations of pesticides under this section shall be carried out in the following phases:

(1) The first phase shall include the listing under subsection (d) of the active ingredients of the pesticides that will be reregistered.

(2) The second phase shall include the submission to the Administrator under subsection (e) of notices by registrants respecting their intention to seek reregistration, identification by registrants of missing and inadequate data for such pesticides, and commitments by registrants to replace such missing or inadequate data within the applicable time period.

(3) The third phase shall include submission to the Administrator by registrants of the information required under subsection (f).

(4) The fourth phase shall include an independent, initial review by the Administrator under subsection (g) of submissions under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, or requests for additional data.

(5) The fifth phase shall include the review by the Administrator under subsection (h) of data submitted for reregistration and appropriate regulatory action by the Administrator.

(d) PHASE ONE.—

(1) PRIORITY FOR REREGISTRATION.—For purposes of the reregistration of the pesticides described in subsection (a), the Administrator shall list the active ingredients of pesticides and shall give priority to, among others, active ingredients (other than active ingredients for which registraion standards have been issued before the effective date of this section) that—

(A) are in use on or in food or feed and may result in postharvest residues;

(B) may result in residues of potential toxicological concern in potable ground water, edible fish, or shellfish;

(C) have been determined by the Administrator before the effective date of this section to have significant outstanding data requirements; or

(D) are used on crops, including in greenhouses and nurseries, where worker exposure is most likely to occur.

(2) REREGISTRATION LISTS.—For purposes of reregistration under this section, the Administrator shall by order—

(A) not later than 70 days after the effective date of this section, list pesticide active ingredients for which registraiton standards have been issued before such date;

(B) not later than 4 months after such effective date, list the first 150 pesticide active ingredients, as determined under paragraph (1);

(C) not later than 7 months after such effective date, list the second 150 pesticide active ingredients, as determined under paragraph (1); and

(D) not later than 10 months after such effective data, list the remainder of the pesticide active ingredients, as determined under paragraph (1).

Each list shall be published in the Federal Register.

(3) JUDICIAL REVIEW.—The content of a list issued by the Administrator under paragraph (2) shall not be subject to judicial review.

(4) NOTICE TO REGISTRANTS.—On the publication of a list of pesticide active ingredients under paragraph (2), the Administrator shall send by certified mail to the registrants of the pesticides containing such active ingredients a notice of the time by which the registrants are to notify the Administrator under subsection (e) whether the registrants intend to seek or not to seek reregistration of such pesticides.

(e) PHASE TWO.—

(1) IN GENERAL.—the registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (d)(2) shall submit to the Administrator, within the time period prescribed by paragraph (4), the notice described in paragraph (2) and any information, commitment, or offer described in paragraph (3).

(2) NOTICE OF INTENT TO SEEK OR NOT TO SEEK REREGISTRATION.—

(A) The registrant of a pesticide containing an active ingredient listed under subparagraph (B), (C), (D) of subsection (d)(2) shall notify the Administrator by certified mail whether the registrant intends to seek or does not intend to seek reregistration of the pesticide.

(B) If the registrant submits a notice under subparagraph (A) of an intention not to seek reregistration of a pesticide, the Administrator shall publish a notice in the Federal Register stating that such a notice has been submitted.

(3) MISSION OR INADEQUATE DATA.—Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (d)(2) and for which the registrant submitted a notice under paragraph (2) of an intention to seek reregistration of such pesticide shall submit to the Administrator—

(A) in accordance with regulations issued by the Administrator under section 3, an identification of—

(i) all data that are required by regulation to support the registration of the pesticide with respect to such active ingredient;

(ii) data that were submitted by the registrant previously in support of the registration of the pesticide that are inadequate to meet such regulations; and

(ii) data identified under clause (i) that have not been submitted to the Administrator; and

(B) either—

(i) a commitment to replace the data identified under subparagraph (A)(ii) and submit the data identified under subparagraph (A)(iii) within the applicable time period prescribed by paragraph (4)(B); or

(ii) an offer to share in the cost to be incurred by a person who has made a commitment under clause (i) to replace or submit the data and an offer to submit to arbitration as described by section 3(c)(2)(B) with regard to such cost sharing.

For purposes of a submission by a registrant under subparagraph (A)(ii), data are inadequate if the data are derived from a study with respect to which the registrant is unable to make the certificatoin prescribed by subsection (f)(1)(G) that the registrant posseses or has acccess to the raw data used in or generated by such study. For purposes of a submission by a registrant under such subparagraph, data shall be considered to be inadequate if the data are devived from a sutdy submitted before January 1, 1970, unless it is demonstrated to the satisfaction of the Administrator that such data should be considered to support the registration of the pesticide that is to be reregistered.

(4) TIME PERIODS.—

(A) A submission under paragraph (2) or (3) shall be made—

(i) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(B), not later than 3 months after the date of publication of the listing of such active ingredient;

(ii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(C), not later than 3 months after the date of publication of the listing of such active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(D), not later than 3 months after the date of publication of the listing of such active ingredient.

On application, the Adminsitrator may extend a time period prescribed by this subparagraph if the Administrator determines that factors beyond the control of the registrant prevent the registrant from complying with such period.

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (3)(B) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period.

(5) CANCELLATION AND REMOVAL.—

(A) If the registrant of a pesticide does not submit a notice under paragraph (3) or (3) within the time prescribed by paragraph (4)(A), the Administrator shall issue a notice of intent to cancel the registration of such registrant for such pesticide and shall publish the notice in the Federal Register and allow 60 days for the submission of comments on the notice. On expiration of such 60 days, the Administrator, by order and without a hearing, may cancel the registration or take such other action, including extension of application time periods, as may be necessary to enable reregistration of such pesticide by another person.

(B)(i) If—

(I) no registrant of a pesticide containing an active ingredient listed under subsection (d)(2) notifies the Administrator under paragraph (2) that the registrant intends to seek reregistration of any pesticide containing that active ingredient;

(II) no such registrant complies with paragraph (3)(A); or

(III) no such registrant makes a commitment under paragraph (3)(B) to replace or submit all data described in clauses (ii) and (iii) of paragraph (3)(A);

the Administrator shall publish in the Federal Register a notice of intent to remove the active ingredient from the list established under subsection (d)(2) and a notice of intent to cancel the registrations of all pesticides containing such active ingredient and shall provide 60 days for comment on such notice.

(ii) After the 60-day period has expired, the Administrator, by order, may cancel any such registration without hearing, except that the Administrator shall not cancel a registration under this subparagraph if —

(I) during the commitment period a person acquires the rights of the registrant in that registration;

(II) during the comment period that person furnishes a notice of intent to reregister the pesticide in accordance with paragraph (2); and

(III) not later than 120 days after the publication of the notice under this subparagraph, that person has complied with paragraph (3) and the fee prescribed by subsection (j)(1) has been paid.

(f) PHASE THREE.—

(1) INFORMATION ABOUT STUDIES.—Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (d)(2) who has submitted a notice under subsection (e)(2) of an intent to seek the reregistration of such pesticide shall submit, in accordance with the guidelines issued under subsection (b)(1), to the Administrator—

(A) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient and considered by the registrant to be adequate to meet the requirements of section 3 and the regulations issued under such section;

(B) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient that may not comply with the requirements of section 3 and the regulations issued under such section 3 and the regulations issued under such section by which the registrant asserts should be deemed to comply with such requirements and regulations;

(C) a reformant of the data from each study summarized under subparagraph (A) or (B) by the registrant concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, teratogenicity, or residue chemistry of the active ingredient that were submitted to the Administrator before January 1, 1982;

(D) where data described in subparagraph (C) are not required for the active ingredient by regulations issued under section 3, a reformat of acute and subchronic dosing data submitted by the registrant to the Administrator before January 1, 1982, that the registrant considers to be adequate to meet the requirements of section 3 and the regulations issued under such section;

(E) an identification of data that are required to be submitted to the Administrator under section 6(g)(4) indicating an adverse effect of the pesticide;

(F) an identification of any other information available that in the view of the registrant supports the registration;

(G) a certification that the registrant or the Administrator possesses or has access to the raw data used in or generated by the studies that the registrant summarized under subparagraph (A) or (B);

(H) either—

(i) a commitment to submit data to fill each outstanding data requirement identified by the registrant; or

(ii) an offer to share in the cost of developing such data to be incurred by a person who has made a commitment under clause (i) to submit such data, and an offer to submit to arbitration as described by section 3(c)(2)(B) with regard to such cost sharing; and

(I) evidence of compliance with section 3(c)(1)(D)(ii) and regulations issued thereunder with regard to previously submitted data as if the registrant were now seeking the original registration of the pesticide.

(2) TIME PERIODS.—

(A) The information required by paragraph (1) shall be submitted to the Administrator—

(i) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(B), not later than 12 months after the date of publication of the listing of such active ingredient.

(ii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(C), not later than 12 months after the date of publication of the listing of such active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(D), not later than 12 months after the date of publication of the listing of such active ingredient.

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (1)(H) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment under such paragraph. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period.

(3) CANCELLATION.—

(A) If the registrant of a pesticide fails to submit the information required by paragraph (1) within the time prescribed by paragraph (2), the Administrator, by order and without hearing, shall cancel the registration of such pesticide.

(B)(i) If the registrant of a pesticide submits the information required by paragraph (I) within the time prescribed by paragraph (2) and such information does not conform to the guidelines for submissions established by the Administrator, the Administrator shall determine whether the registant made a good faith attempt to conform its submission to such guidelines.

(ii) If the Administrator determines that the registrant made a good faith attempt to conform its submission to such guidelines, the Administrator shall provide the registrant a reasonable period of time to make any necessary changes or corrections.

(iii)(I) If the Administrator determines that the registrant did not make a good faith attempt to conform its submission to such guidelines, the Administrator may issue a notice of intent to cancel the registration. Such a notice shall be sent to the registrant by certified mail.

(II) The registration shall be canceled without a hearing or further notice at the end of 30 days after receipt by the registrant of the notice unless during that time a request for a hearing is made by the registrant.

(III) If a hearing is requested, a hearing shall be conducted under section 6(d), except that the only matter for resolution at the hearing shall be whether the registrant made a good faith attempt to conform its submission to such guidelines. The hearing shall be held and a determination made within 75 days after receipt of request for hearing.

(g) PHASE FOUR.—

(1) INDEPENDENT REVIEW AND IDENTIFICATION OF OUTSTANDING DATA REQURIEMENTS.—

(A) The Administrator shall review the submissions of all registrants of pesticides containing a particular active ingredient under subsections (e)(3) and (f)(1) to determine if such submissions identified all the data that are missing or inadequate for such active ingredient. To assist the review of the Administrator under this subparagraph, the Administrator may require a registrant seeking reregistration to submit complete copies of studies summarized under subsection (f)(1).

(B) The Administrator shall independently identify and publish in the Federal Register the outstanding data requirements for each active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (d)(2) and that is contained in a pesticide to be reregistered under this section. The Administrator, at the same time, shall issue a notice under section 3(c)(2)(B) for the submission of the additional data that are required to meet such requirements.

(2) TIME PERIODS.—

(A) The Administrator shall take the action required by paragraph (I)—

(i) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(B), not later than 18 months after the date of the listing of such active ingredient:

(ii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(C), not later than 24 months after the date of the listing of such active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (d)(2)(D), not later than 33 months after the date of the listing of such active ingredient.

(B) If the Administrator issues a notice to a registrant under paragraph (1)(B) for the submission of aditional data, the registrant shall submit such data within a reasonable period of time, as determined by the Administrator, but not to exceed 48 months after the issuance of such notice. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant form submitting data within such prescribed period.

(h) PHASE FIVE.—

(1) DATA REVIEW.—The Administrator shall conduct a thorough examination of all data submitted under this section concerning an active ingredient listed under subsection (d)(2) and of all other available data found by the Administrator to be relevant.

(2) REREGISTRATION AND OTHER ACTIONS.—

(A) Within 1 year after the submission of all data concerning an active ingredient of a pesticide under subsection (g), the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration. For extraordinary circumstances, the Administrator may extend such period for not more than 1 additional year.

(B) Before reregistering a pesticide, the Administrator shall obtain any needed product-specific data regarding the pesticide by use of section 3(c)(2)(B) and shall review such data within 90 days after its submission. The Administrator shall require that data under this subparagraph be submitted to the Administrator not later then 8 months after a determination of eligibility under subparagraph (A) has been made for each active ingredient of the pesticide, unless the Administrator determines that a longer period is required for the generation of the data.

(C) After conducting the review required by paragraph (1) for each active ingredient of a pesticide and the review required by subparagraph (B) of this paragraph, the Administrator shall determine whether to reregister a pesticide by determining whether such pesticide meets the requirements of section 3(c)(5). If the Administrator determines that a pesticide is eligible to be reregistered, the Administrator shall reregister such pesticide within 6 months after the submission of the data concerning such pesticide under subparagraph (B).

(D) If after conducting a review under paragraph (1) or subparagraph (B) of this paragraph the Administrator de-

termines that a pesticide should not be reregistered, the Administrator shall take appropriate regulatory action.

(i) COMPENSATION OF DATA SUBMITTER.—If data that are submitted by a registrant under subsection (e), (f), (g), or (h) are used to support the application of another person under section 3, the registrant who submitted such data shall be entitled to compensation for the use of such data as prescribed by section 3(c)(1)(D). In determining the amount of such compensation, the fees paid by the registrant under this section shall be taken into account.

(j) FEES.—

(1) INITIAL FEE FOR FOOD OR FEED USE PESTICIDE ACTIVE INGREDIENTS.—The registrants of pesticides that contain an active ingredient that is listed under subparagraphs (B), (C), or (D) of subsection (d)(2) and that is an active ingredient of any pesticide registered for a major food or feed use shall collectively pay a fee of $50,000 on submission of information under paragraphs (2) and (3) of subsection (e) for such ingredient.

(2) FINAL FEE FOR FOOD OR FEED USE PESTICIDE ACTIVE INGREDIENTS.—

(A) The registrants of pesticides that contain an active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (d)(2) and that is an active ingredient of any pesticide registered for a major food or feed use shall collectively pay a fee of $100,000—

(i) on submission of information for such ingredient under subsection (f)(1) if data are reformatted under subsection (f)(1)(C); or

(ii) on submission of data for such ingredient under subsection (f)(2)(B) if data are not reformatted under subsection (f)(1)(C).

(B) The registrants of pesticides that contain an active ingredient that is listed under subsection (d)(2)(A) and that is an active ingredient of any pesticide registered for a major food or feed use shall collectively pay a fee of $150,000 at such time as the Administrator shall prescribe.

(3) FEES FOR OTHER PESTICIDE ACTIVE INGREDIENTS.—

(A) The registrants of pesticides that contain an active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (d)(2) and that is not an active ingredient of any pesticide registered for a major food or feed use shall collectively pay fees in amounts determined by the Administrator. Such fee may not be less than one-half of, nor greater than, the fees required by paragraphs (1) and (2). A registrant shall pay such fees at the times corresponding to the times fees prescribed by paragraphs (1) and (2) are to be paid.

(B) The registrants of pesticides that contain an active ingredient that is listed under subsection (d)(2)(A) and that is not an active ingredient of any pesticide that is registered for a major food or feed use shall collectively pay a fee of not more than $100,000 and not less than $50,000 at such time as the Administrator shall prescribe.

(4) REDUCTION OR WAIVER OF FEES FOR MINOR USE AND OTHER PESTICIDES.—

(A) An active ingredient of a pesticide that is registered solely for an agricultural or nonagricultural minor use, or a pesticide the value or volume of use of which is small, shall be exempt from the fees prescribed by paragraph (3).

(B) An antimicrobial active ingredient, the production level of which does not exceed 1,000,000 pounds per year, shall be exempt from the fees prescribed by paragraph (3).

(C)(i) Notwithstanding any other provision of this subsection, in the case of a small business registrant of a pesticide, the registrant shall pay a fee for the reregistration of each active ingredient of the pesticide that does not exceed an amount determined in accordance with this subparagraph.

(ii) If during the 3-year period prior to reregistration the average annual gross revenue of the registrant from pesticides containing such active ingredient is—

(I) less than $5,000,000, the registrant shall pay 0.5 percent of such revenue;

(II) $5,000,000 or more but less than $10,000,000, the registrant shall pay 1 percent of such revenue; or

(III) $10,000,000 or more, the registrant shall pay 1.5 percent of such revenue, but not more than $150,000.

(iii) For the purpose of this subparagraph, a small business registrant is a corporation, partnership, or unincorporated business that—

(I) has 150 or fewer employees; and

(II) during the 3-year period prior to reregistration, had an average annual

(C)(i) The maximum annual fee payable by a registrant under clause (i) of subparagraph (A) as adjusted under subparagraph (B)) shall be $20,000.

(ii) The maximum annual fee payable by a registrant under clauses (i) and (ii) of subparagraph (A) (as adjusted under subparagraph (B)) shall be $35,000.

(D) If any fee prescribed by this paragraph with respect to the registration of a pesticide is not paid by a registrant by the time prescribed, the Administrator, by order and without hearing, may cancel the registration.

(E) The authority provided under this paragraph shall terminate on September 30, 1997.

(6) OTHER FEES.—During the period beginning on the date of enactment of this section and ending on September 30, 1997, the Administrator may not levy any other fees for the registration of a pesticide under this Act except as provided in paragraphs (1) through (5).

(7) APPORTIONMENT.—

(A) If two or more registrants are required to pay any fee prescribed by paragraph (1), (2), or (3) with respect to a particular active ingredient, the fees for such active ingredient shall be apportioned among such registrants on the basis of the market share in United States sales of the active ingredient for the 3 calendar years preceding the date of payment of such fee, except that—

(i) small business registrants that produce the active ingredient shall pay fees in accordance with paragraph (4)(C); and

(ii) registrants who have no market share but who choose to reregister a pesticide containing such active ingredient shall pay the lesser of—

(I) 15 percent of the reregistration fee; or

(II) a proportionate amount of such fee based on the lowest percentage market share held by any registrant active in the marketplace.

In no event shall registrants who have no market share but who choose to reregister a pesticide containing such active ingredient collectively pay more than 25 percent of the total active ingredient reregistration fee.

(B) The Administrator, by order, may require any registrant to submit such reports as the Administrator determines to be necessary to allow the Administrator to determine and apportion fees under this subsection or to determine the registrant's eligibility for a reduction or waiver of a fee.

(C) If any such report is not submitted by a registrant after receiving notice of such report requirement, or if any fee prescribed by this subsection (other than paragraph (5)) for an active ingredient is not paid by a registrant to the Administrator by the time prescribed under this subsection, the Administrator, by order and without hearing, may cancel each registration held by such registrant of a pesticide containing the active ingredient with respect to which the fee is imposed. The Administrator shall reapportion the fee among the remaining registrants and notify the registrants that the registrants are required to pay to the Administrator any unpaid balance of the fee within 30 days after receipt of such notice.

(k) EXEMPTION OF CERTAIN REGISTRANTS.—The requirements of subsections (e), (f), (g), and (j) other than subsection (j)(5)) regarding data concerning an active ingredient and fees for review of such data shall not apply to any person who is the registrant of a pesticide to the extent that, under section 3(c)(2)(D), the person would not be required to submit or cite such data to obtain an initial registration of such pesticide.

(l) REREGISTRATION AND EXPEDITED PROCESSING FUND.—

(1) ESTABLISHMENT.—There shall be established in the Treasury of the United States a reregistration and expedited processing fund.

(2) SOURCE AND USE.—All fees collected by the Administrator under subsection (j) shall be deposited into the fund and shall be available to the Administrator, without fiscal year limitation, to carry out reregistration and expedited processing of similar applications.

(3) EXPEDITED PROCESSING OF SIMILAR APPLICATIONS.—

(A) The administrator shall use each fiscal year not more than $2,000,000 of the amounts in the fund to obtain sufficient personnel and resources to assure the expedited processing and review of any application that—

(i) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from any such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; or

(ii) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data.

(B) Any amounts made available under subparagraph (A) shall be used to obtain sufficient personnel and resources to carry out the activities described in such subparagraph that are in addition to the personnel and resources available to carry out such activities on the date of enactment of this section.

(4) UNUSED FUNDS.—Money in the fund not currently needed to carry out this section shall be—

(A) maintained on hand or on deposit;

(B) invested in obligations of the United States or guaranteed thereby; or

(C) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

(5) ACCOUNTING.—The Administrator shall—

(A) provide an annual accounting of the fees collected and disbursed from the fund; and

(B) take all steps necessary to ensure that expeditures of such funds are used only to carry out this section.

(m) JUDICIAL REVIEW.—Any failure of the Administrator to take any action required by this section shall be subject to judicial review under the procedures prescribed by section 16(b).

SEC. 5. EXPERIMENTAL USE PERMITS.

(a) ISSUANCE.—Any * * *

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(f) STATE ISSUANCE OF PERMITS.—Notwithstanding the foregoing provisions of this section, the Administrator shall, under such terms and conditions as he may by regulation prescribe, authorize any State to issue an experimental use permit for a pesticide. All provisions of [section 4] *section 11* relating to State plans shall apply with equal force to a State plan for the issuance of experimental use permits under this section.

* * * * * * *

(g) EXEMPTION FOR AGRICULTURAL RESEARCH AGENCIES.—Notwithstanding the foregoing provisions of this section, the Administrator may issue an experimental use permit for a pesticide to any public or private agricultural research agency or educational institution which applies for such permit. Each permit shall not exceed more than a one-year period or such other specific time as the Administrator may prescribe. Such permit shall be issued under such

terms and conditions restricting the use of the pesticide as the Administrator may require[: *Provided,* That such]. *Such* pesticide may be used only by such research agency or educational institution for purposes of experimentation.

SEC. 6. ADMINISTRATIVE REVIEW; SUSPENSION.

(a) CANCELLATION AFTER FIVE YEARS.—

[(1) PROCEDURE.—] The Administrator shall cancel the registration of any pesticide at the end of the five-year period which begins on the date of its registration (or at the end of any five-year period thereafter) unless the registrant, or other interested person with the concurrence of the registrant, before the end of such period, requests in accordance with regulations prescribed by the Administrator that the registration be continued in effect[: *Provided,* That the Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is canceled under this subsection or subsection (b) to such extent, under such conditions, and for such uses as he may specify if he determines that such sale or use is not inconsistent with the purposes of this Act and will not have unreasonable adverse effects on the environment]. The Administrator shall publish in the Federal Register, at least 30 days prior to the expiration of such five-year period, notice that the registration will be canceled if the registrant or other interested person with the concurrence of the registrant does not request that the registration be continued in effect.

[(2) INFORMATION.—If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator.]

[(b) CANCELLATION AND CHANGE IN CLASSIFICATION.—If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this Act or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of his intent either—

[(1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for his action, or

[(2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

Such notice shall be sent to the registrant and made public. In determining whether to issue any such notice, the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy. At least 60 days prior to sending such notice to the registrant or making public such notice, whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of such notice and an analysis of such impact on the agricultural economy. If the Secretary comments in writing to the Administrator regarding the notice and analysis within 30

days after receiving them, the Administrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the notice and analysis within 30 days after reciving them, the Administrator may notify the registrant and make public the notice at any time after such 30-day period notwithstanding the foregoing 60-day time requirement. The time requirements imposed by the preceding 3 sentences may be waived or modified to the extent agreed upon by the Administrator and the Secretary. Notwithstanding any other provision of this subsection (b) and section 25(d), in the event that the Administrator determines that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, then upon such a finding the Administrator may waive the requirement of notice to and consultation with the Secretary of Agriculture pursuant to subsection (b) and of submission to the Scientific Advisory Panel pursuant to section 25(d) and proceed in accordance with subsection (c). The proposed action shall become final and effective at the end of 30 days from receipt by the registrant, or publication, or a notice issued under paragraph (1), whichever occurs later, unless within that time either (i) the registrant makes the necessary corrections, if possible, or (ii) a request for a hearing is made by a person adversely affected by the notice. In the event a hearing is held pursuant to such a request or to the Administrator's determination under paragraph (2), a decision pertaining to registration or classification issued after completion of such hearing shall be final. In taking any final action under this subsection, the Administrator shall consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and shall include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and he shall publish in the Federal Register an analysis of such impact.]

(b) CANCELLATION AND CHANGE IN CLASSIFICATION OR LABELS.—

(I) NOTICE OF CANCELLATION OR CHANGE IN CLASSIFICATION.—

(A) If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with this Act or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of intent—

(i) to cancel its registration or to chang its classification, together with the reasons (includin the factual basis) for the action of the Administrator; r

(ii) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

(B) A notice issued under subparagraph (A) shall be sent to each registrant of the pesticide with respect to which the notice is issued and shall be made public.

(C) In determining whether to issue a notice under subparagraph (A), the Administrator shall include among

those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy.

(D)(i) Not later than 60 days before sending a notice to a registrant or making public such notice under subparagraph (B), whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of the proposed notice under subparagraph (A) and an analysis of the impact of the proposed action on the agricultural economy. The Secretary of Agriculture shall provide comments on such notice and analysis to the Administrator within 30 days after receiving the copy of such notice.

(ii)(I) If the Secretary of Agriculture provides such comments in writing within 30 days after receiving the copy of such notice, the Administrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the comments of the Secretary.

(II) If the Secretary of Agriculture does not provide such comments in writing within 30 days after receiving the copy of such notice, the Administrator may notify the registrant and make public the notice at any time after such 30-day period.

(iii) The time requirements imposed by this subparagraph may be waived or modified to the extent agreed on by the Administrator and the Secretary of Agriculture.

(E) If the Administrator finds that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, the Administrator may waive the requirements of notice to the Secretary of Agriculture prescribed in subparagraph (D) and submission to the Scientific Advisory Panel under section 25(d) and proceed in accordance with subsection (c).

(2) HEARING.—

(A) The action proposed in a notice issued under paragraph (I)(A) shall become final and effective at the end of 30 days after receipt by the registrant or publication of a notice issued under paragraph (1)(B), whichever occurs later, unless within that time—

(i) the registrant makes the necessary corrections, if possible; or

(ii) a request for a hearing is made by a person adversely affected by the notice.

(B) Whenever a request for a hearing is made, the request shall—

(i) identify with particularity the findings and conclusions of the decision of the Administrator that are disputed; and

(ii) include a complete statement of the reasons and factual basis that support the request for a hearing.

(C) Any party to the proceeding may identify findings and conclusions in dispute.

(D) If a hearing is held pursuant to such a request or the determination of the Administrator under paragraph (1)(A)(ii), a decision pertaining to registration or classification issued after completion of such hearing shall be final.

(E) On receipt of a request for a hearing from a person without an economic interest in the pesticide with respect to which the hearing is requested, the Administrator shall convene such hearing if the request presents a substantial issue of fact, as determined by the Administrator, pertaining to whether such pesticide poses an unreasonable risk to man or the environment.

(3) FACTORS.—In taking any action under paragraph (1), the Administrator shall—

(A) consider restricting a use or uses of a pesticide as an alternative to cancellation and fully explain the reasons for such restriction; and

(B) consider the impact of such action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and publish in the Federal Register an analysis of such impact.

(4) LABEL CHANGES.—

(A)(i) If the Administrator proposes a label change, the Administrator may—

(I) notify the registrant of a pesticide of the label change proposed by the Administrator; and

(II) provide that the registrant may submit comments to the Administrator on such proposed change during the 30-day period beginning on the date of the receipt of such notice.

(ii) If a registrant who is notified by the Administrator of a proposed label change notifies the Administrator that the registrant does not object to such change, such change shall take effect as prescribed by the Administrator.

(iii) If a registrant who is notified by the Administrator of a proposed label change does not submit comments to the Administator in such 30-day period, the Administrator shall send such registrant a second notice stating that, if such registrant does not submit any comments to the Administrator in the 30-day period beginning on the date the registrant receives the second notice, the registration of such registrant shall be canceled without a hearing or further notice. The registration of a registrant who does not submit comments on the second notice within such 30-day period shall be canceled without further notice.

(iv) If in response to a notice under this subparagraph a registrant submits comments to the Administrator objecting to a proposed label change, the Administrator shall proceed under subparagraph (B).

(B) If the label change proposed by the Administrator alters the areas or methods of permissible application, crops on which the pesticide may be used, or other use of the pesticide, or if a registrant has objected to a label change proposed by the Administrator.

(i) The Administrator may, after notice in the Federal Register and not less than 45 days of comment, require changes to the label of a pesticide by informal rulemaking under this paragraph unless the Administrator finds the changes—

(I) are equivalent to a cancellation of a use;

(II) render the pesticide unmarketable; or

(III) otherwise have a major economic impact on persons affected by such changes.

Such notice in the Federal Register shall include a full description of the proposed label changes and a statement of the economic impact of the proposed lael change on users of the pesticide and the public at large.

(ii) If the Administrator is precluded from requiring changes to the label of a pesticide by informal rulemaking under this subparagraph, the Administrator may only require such changes by a proceeding authorized by section 6.

(C)(i) After the promulgation of a regulation under subparagraph (B), the Administrator shall—

(I) notify each registrant of the pesticide subject to the regulation of the label change required by the regulation; and

(II) provide a 30-day period for each registrant to apply to the Administrator for an amendment to the registration to comply with the regulation.

(ii) If a registrant does not apply for such an amendment within such period, the Administrator shall issue a notice of intent to cancel the registration of such registrant in accordance with paragraph (2). For purposes of paragraph (2), such notice shall be deemed to have been issued under paragraph (1).

(D) A registrant or user of a pesticide subject to a regulation issued under subparagraph (B) may request a hearing under subsection (d) on such regulation in accordance with paragraph (2). The scope of the hearing shall be limited to—

(i) whether the pesticide complies with the regulation;

(ii) whether the regulation by its terms is applicable to such pesticide; and

(iii) whether, because of significant information that was not (and could not reasonably have been) presented in the proceeding wherein the regulation was promulgated, it would be unreasonable to require such pesticide to comply with the regulation.

(E)(i) Except as provided in clause (ii), in an action under section 16(e) for review of a regulation issued under subparagraph (B), the court, on request, shall postpone the effective date of the regulation until completion of the review action if the petitioner shows—

(I) a likelihood of success on the merits in such action; and

(II) that the implementation of the regulation before completion of the action would cause a risk of substantial harm to the petitioner.

(ii) A court in a review action under section 16(e) shall not postpone the effective date of a regulation issued under subparagraph (B) if the Administrator shows that failure to implement the regulation before completion of the action would cause a risk of substantial harm to health or the environment.

(c) SUSPENSION.—

(1) ORDER.—If the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings, he may, by order, suspend the registration of the pesticide immediately. No order of suspension may be issued unless the Administrator has issued or at the same time issues notice of his intention to cancel the registration or change the classification of the pesticide. Except as provided in paragraph (3), the Administrator shall notify the registrant prior to issuing any suspension order. Such notice shall include findings pertaining to the question of "imminent hazard". The registrant shall then have an opportunity, in accordance with the provisions of paragraph (2), for an expedited hearing before the [Agency] *Administrator* on the question of whether an imminent hazard exists.

(2) EXPEDITE HEARING.—If no request for a hearing is submitted to the [Agency] *Administrator* within five days of the registrant's receipt of the notification provided for by paragraph (1), the suspension order may be issued and shall take effect and shall not be reviewable by a court. If a hearing is requested, it shall commence within five days of the receipt of the request for such hearing unless the registrant and the [Agency] *Administrator* agree that it shall commence at a later time. The hearing shall be held in accordance with the provisions of subchapter II of title 5 of the United States Code, except that the presiding officer need not be a certified hearing examiner. The presiding officer shall have ten days from the conclusion of the presentation of evidence to submit recommended findings and conclusions to the Administrator, who shall then have seven days to render a final order on the issue of suspension.

(3) EMERGENCY ORDER.—Whenever the Administrator determines that an emergency exists that does not permit him to hold a hearing before suspending, he may issue a suspension order in advance of notification to the registrant. In that case, paragraph (2) shall apply except that [(i)] *(A)* the order of suspension shall be in effect pending the expeditious completion of the remedies provided by that paragraph and the issuance of a final order on suspension, and [(ii)] *(B)* no party other than the registrant and the [Agency] *Administrator* shall participate except that any person adversely affected may file briefs within the time allotted by the Agency's rules. Any person so filing briefs shall be considered a party to such proceeding for the purposes of section 16(b).

(4) JUDICIAL REVIEW.—A final order on the question of suspension following a hearing shall be reviewable in accordance with Section 16 of this Act, notwithstanding the fact that any related cancellation proceedings have not been completed. Any order of suspension entered prior to a hearing before the Administrator shall be subject to immediate review in an action by the registrant or other interested person with the concurrence of the registrant in an appropriate district court, solely to determine whether the order of suspension was arbitrary, capricious or an abuse of discretion, or whether the order was issued in accordance with the procedures established by law. The effect of any order of the court will be only to stay the effectiveness of the suspension order, pending the Administrator's final decision with respect to cancellation or change in classification. This action may be maintained simultaneously with any administrative review proceeding under this section. The commencement of proceedings under this paragraph shall not operate as a stay or order, unless ordered by the court.

(d) PUBLIC HEARINGS [AND SCIENTIFIC REVIEW].—In the event a hearing is requested pursuant to subsection (b) or determined upon by the Administrator pursuant to subsection (b), such hearing shall be held after due notice for the purpose of receiving evidence relevant and material to the issues raised by the objections filed by the applicant or other interested parties, or to the issues stated by the Administrator, if the hearing is called by the Administrator rather than by the filing of objections. Upon a showing of relevance and reasonable scope of evidence sought by any party to a public hearing, the Hearing Examiner shall issue a subpena to compel testimony or production of documents from any person. The Hearing Examiner shall be guided by the principles of the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, the subpena may be enforced by an appropriate United States district court in accordance with the principles stated herein. [Upon the request of any party to a public hearing and when in the Hearing Examiner's judgment it is necessary or desirable, the Hearing Examiner shall at any time before the hearing record is closed refer to a Committee of the National Academy of Sciences the relevant questions of scientific fact involved in the public hearing. No member of any committee of the National Academy of Sciences established to carry out the functions of this section shall have a financial or other conflict of interest with respect to any matter considered by such committee. The Committee of the National Academy of Sciences shall report in writing to the Hearing Examiner within 60 days after such referral on these questions of scientific fact. The report shall be made public and shall be considered as part of the hearing record. The Administrator shall enter into appropriate arrangements with the National Academy of Sciences to assure an objective and competent scientific review of the questions presented to Committees of the Academy and to provide such other scientific advisory services as may be required by the Administrator for carrying out the purposes of this Act.] As soon as practicable after completion of the

hearing [(including the report of the Academy)] but not later than [90 days thereafter] *18 months after issuance of the notice that gave rise to the hearing*, the Administrator shall evaluate the data and reports before him and issue an order either revoking his notice of intention issued pursuant to this section, or shall issue an order either canceling the registration, changing the classification, denying the registration, or requiring modification of the labeling or packaging of the article. *The time period prescribed by the preceding sentence may be extended by the Administrator under extraordinary circumstances for not more than 1 year.* Such order shall be based only on substantial evidence of record of such hearing and shall set forth detailed findings of fact upon which the order is based.

(e) CONDITIONAL REGISTRATION.—

(1) the Administrator shall issue a notice of intent to cancel a registration issued under section 3(c)(7) of this Act if (A) the Administrator, at any time during the period provided for satisfaction of any condition imposed, determines that the registrant has failed to initiate and pursue appropriate action toward fulfilling any condition imposed, or (B) at the end of the period provided for satisfaction of any condition imposed, that condition has not been met: *Provided,* That the Administrator may permit the continued sale and use of existing stocks of a pesticide whose conditional registration has been canceled under this subsection to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator determines that such sale or use is not inconsistent with the purposes of this Act and will not have unreasonable adverse effects on the environment.

(2) A cancellation proposed under this subsection shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to cancel unless during that time a request for hearing is made by a person adversely affected by the notice. If a hearing is requested, a hearing shall be conducted under subsection (d) of this section. [: *Provided,* That the only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act. A decision after completion of such hearing shall be final. Notwithstanding any other provision of this section, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing.]

(f) HEARING PROCEDURES AFTER PUBLIC INTERIM ADMINISTRATIVE REVIEW.—

(1) GENERAL RULE.—Except as provided in paragraphs (2) and (3), subsection (d) shall govern any hearing under such subsection—

(A) that results from the final determination of the Administrator in a public interim administrative review pro-

ceeding under section 3(c)(8) that is initiated after the date that is 1 year after the date of enactment of this subsection;

(B) that includes an opportunity for comment on a notice of preliminary determination issued in connection with such review; and

(C) for which the time between the first public notice for such review under section 3(c)(8)(F) and the close of the last comment period provided for such review is not less than 180 days.

(2) REQUEST FOR HEARING.—Any person who is adversely affected by a decision of the Administrator respecting a pesticide (including a person without an economic interest in such pesticide) following a public interim administrative review described by paragraph (1) may request, or intervene in a hearing in the manner provided by subsection (b)(2)(B) within 30 days after such decision. A person may request a hearing, or intervene in a hearing, only if that person submitted comments during the public interim administrative review proceeding and otherwise complied with section 3(c)(8)(F).

(3) PROCEDURES.—

(A) At the request of a party, an administrative law judge conducting a hearing may receive into evidence portions of a public interim administrative review record and other evidence, if the party demonstrates that such portions of the record and other evidence are relevant and material to the disputed issues and are not unduly repetitious, and if a competent witness is made available to be cross-examined on all matters relating to such evidence. Direct testimony of witnesses concerning scientific data or studies that were not, but could have been, obtained and submitted in the public interim administrative review proceeding by the exercise of due diligence by the offering party shall not be admissible.

(B) The right of other parties to confront and cross-examine witnesses with respect to such evidence shall be preserved with respect to material issues of adjudicative fact, so long as such cross-examination is not unduly repetitious.

(C)(i) Not later than 120 days after an administrative law judge is appointed, prehearing matters shall be completed and the hearing shall commence.

(ii) The administrative law judge may establish a schedule for prehearing matters, including discovery and motions, and shall ensure that the hearing schedule is met. The administative law judge shall issue such orders as are appropriate for the purpose of simplifying and clarifying issues, specifying the order of presentation of witnesses, and allocating the time for cross-examination, briefing, and decision.

(iii) Discovery shall be permitted after the expiration of 120 days after the appointment of the administrative law judge on a determination by the administrative law judge that—

(I) such discovery shall not in any way unreasonably delay the proceeding;

(II) the information to be obtained is not otherwise obtainable; and

(III) such information has significant probative value and is necessary to obtain relevant evidence needed to resolve a material issue in dispute.

(D) Any challenge to—

(i) the authority to issue; or

(ii) the procedural correctness of the issuance of,

any notice of intent to cancel or change classification or to any request for a hearing or motion to intervene shall be filed with the administrative law judge not later than 30 days before the commencement of the evidentiary phase of the hearing.

(E) Not later than 30 days before the hearing commences, each party shall make available to the other parties the names of the expert and other witnesses the party expects to call, together with a brief narrative summary of their expected testimony and a list of all documents and exhibits that the party expects to introduce into evidence. Thereafter, witnesses, documents, or exhibits may be added and narrative summaries of expected testimony amended on motion by a party.

(F) If new studies become available that were not available during the public interim administrative review, the administrative law judge, on request of any party and when in the judgment of the administrative law judge it is necessary, may submit such studies to the Scientific Advisory Panel established under section 25(d) for supplemental comment on an expedited basis under such time limits as may be established by the administrative law judge.

(G) The administrative law judge shall schedule the presentation and examination of witnesses so that the presentation of evidence is completed within 60 days after the commencement of the hearing, except that the schedule shall not prejudice the right of a party to present evidence. The person who requested a hearing on an issue shall have the burden of going forward to present an affirmative case and shall have the burden of proof as to that issue.

(H) A hearing conducted in accordance with this subsection shall be completed and the Administrator shall make a final decision within 300 days after the issuance of the notice that gave rise to the hearing. The time limit imposed by this subparagraph may not be extended, except in exceptional circumstances in which such extension is essential for a fair and accurate determination of pivotal facts central to the proceeding. In no event may such time limit be extended more than 180 days. Any other time limit imposed by this paragraph may be extended for good cause.

(I) Failure to complete a hearing and make a final decision within the time period prescribed by subparagraph (H) shall be grounds for a civil action in a district court of the United States seeking an order to establish a schedule requiring the prompt completion of the hearing, but shall not be grounds for termination of the hearing or for making a

final decision respecting the pesticide that is the subject of the hearing.

(g) GENERAL PROVISIONS.—

(1) VOLUNTARY CANCELLATION.—A registrant at any time may request that any of its pesticide registrations be canceled or be amended to delete one or more uses. Before acting on such request, the Administrator shall publish in the Federal Register a notice of the receipt of the request. Thereafter, the Administrator may approve such a request.

(2) PUBLICATION OF NOTICE.—A notice of denial of registration, intent to cancel, suspension, or intent to suspend issued under this Act, a notice issued under subsection (d)(4) or (e)(5)(A) of section 4, or a notice issued under the third sentence of subsection (b)(4)(A), shall be published in the Federal Register and shall be sent by certified mail, return receipt requested, to the registrant's or applicant's address of record on file with the Administrator. If the mailed notice is returned to the Administrator as undeliverable at that address, if delivery is refused, or if the Administrator otherwise is unable to accomplish delivery of the notice to the registrant or applicant after making reasonable efforts to do so, the notice shall be deemed to have been received by the registrant or applicant on the date the notice was published in the Federal Register.

(3) EXISTING STOCKS.—The Administrator may permit the continued use, distribution, or sale, or any combination thereof, of existing stocks of a pesticide whose registration is canceled under this Act to such extent, under such conditions, during such periods, and for such uses as the Administrator may specify if the Administrator determines that such distribution, sale, or use is not inconsistent with the purposes of this Act and will not cause unreasonable adverse effects on the environment.

(4) ADDITIONAL INFORMATION.—If at any time after the registration of a pesticide the registrant has additional information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator. For purposes of this paragraph, the term "information" includes factual information and expert opinion regarding risks or benefits.

(h) SUSPENSION AND CANCELLATION OF REGISTRATION BASED ON FALSE OR INVALID DATA.—

(1) NOTICE.—

(A) The Administrator shall immediately issue an order of suspension and a notice of intent to cancel the registration of a pesticide if—

(i) before the effective date of this subsection, the Administrator has previously determined in the Industrial Biotest validation process conducted by the Administrator that data submitted by the registrant of the pesticide to the Administrator in support of such registration were invalid;

(ii) the data referred to in clause (i)—

(I) have not been replaced as of the effective date of this subsection; or

(II) are in the process of being replaced on the effective date of this subsection but were not submitted to the Administrator by April 1, 1988; and

(iii) such data are material to the registration.

(B) The Administrator may issue an order of suspension and a notice of intent to cancel the registration of a pesticide by a registrant who cited data described in subparagraph (A) in support of the registration of the pesticide.

(2) INVALID DATA.—

(A) If, after the effective date of this subsection, the Administrator determines that invalid data are submitted by a registrant to the Administrator in support of a registration of a pesticide, the Administrator may—

(i) require the registrant to submit valid replacement studies or data on an expedited schedule and to submit interim progress reports; or

(ii) issue a notice of intent to cancel such registration if the Administrator determines that such action would be in the public interest, taking into account the scope of the invalid data and the need to use the data to determine whether the pesticide may cause unreasonable adverse effects on the environment.

(B) If, after the effective date of this subsection, the Administrator determines that invalid data are cited by a registrant to the Administrator in support of a registration of a pesticide, the Administrator may—

(i) require the registrant to submit valid replacement studies or data on an expedited schedule and to submit interim progress reports; or

(ii) issue a notice of intent to cancel such registration if the Administrator determines that such action would be in the public interest, taking into account the scope of the invalid data and the need to use the data to determine whether the pesticide may cause unreasonable adverse effects on the environment.

(3) FALSE DATA.—If a registrant willfully submits material data known to be false in support of the registration of a pesticide, the Administrator shall immediately issue notices of intent to suspend and cancel such registration.

(4) HEARING.—

(A) Any suspension or cancellation under this subsection shall become final and effective at the end of the 30-day period beginning on the date of receipt by the registrant of a notice issued under this subsection unless during such period a request for a hearing is made by a person adversely affected.

(B) A hearing under this paragraph shall be conducted in accordance with the procedures prescribed by subsection (c) or (d), as appropriate.

(C) In the case of a hearing held with respect to action proposed to be taken under paragraph (1), the only matters for resolution shall be whether—

(i) in response to a notice of the Administrator issued under section 3(c)(2)(B) or other formal notice, data pre-

viously determined by the Administrator to be invalid—

(I) have not been replaced as of the effective date of this subsection; or

(II) are in the process of being replaced on the effective date of this subsection but were not submitted to the Administrator by April 1, 1988; and

(ii) the data are material to the registration.

(D) In the case of a hearing held with respect to action proposed to be taken under paragraph (2), the only matters for resolution shall be whether data are invalid, material, and necessary to adquately determine whether a pesticide may cause unreasonable adverse effects on the environment.

(E) In the case of a hearing held with respect to action proposed to be taken under paragraph (3) the only matters for resolution shall be whether a registrant willfully submitted material data known to be false.

(F) A decision after completion of a hearing conducted under this paragraph shall be final.

(G) Notwithstanding any other provision of this Act, a hearing shall be held, and a determination made, under this subsection within 75 days after receipt of a request for such hearing.

(i) NOTICE FOR STORED PESTICIDES WITH CANCELED OR SUSPENDED REGISTRATIONS.—

(1) IN GENERAL.—Any producer or exporter of a pesticide, registrant of a pesticide, applicant for registration of a pesticide, applicant for or holder of an experimental use permit, pesticide testing facility, commercial applicator, or any person who distributes or sells any pesticide, the registration of which has been canceled or suspended under this section, shall notify the Administrator and the appropriate State and local officials, in such manner and within such time as the Administrator shall prescribe by regulation or as part of an order issued under this section, of—

(A) such possession;

(B) the quantity of such pesticide in its possession; and

(C) the place at which such pesticide is stored.

(2) COPIES.—The Administrator shall transmit a copy of each notice submitted under this subsection to the regional office of the Environmental Protection Agency that has jurisdiction over the place of pesticide storage identified in the notice.

[(f)**]***(j)* JUDICIAL REVIEW.—Final orders of the Administrator under this section shall be subject to judicial review pursuant to section 16.

SEC. 7. REGISTRATION OF ESTABLISHMENTS.

(a) REQUIREMENT.—* * *

* * * * * * *

(c) INFORMATION REQUIRED.—

(1) Any producer operating an establishment registered under this section **[**shall inform the Administrator**]** *shall, in accordance with regulations promulgated by the Administrator, submit to the Administrator a report* within 30 days after it is

registered [of the] *describing* types and amounts of pesticides and, if applicable, active ingredients used in producing pesticides—

(A) which he is currently producing—

(B) which he has produced during the past year; and

(C) which he has sold or distributed during the past year.

The [information] *report* required by this paragraph shall be kept current and submitted to the Administrator annually as required under such regulations as the Administrator may prescribe.

(d) CONFIDENTIAL RECORDS AND INFORMATION.—Any information submitted to the Administrator pursuant to subsection (c) other than the names *and production locations* of the pesticides or active ingredients used in producing pesticides produced, sold, or distributed at an establishment shall be considered confidential and shall be subject to the provisions of section 10.

(e) PUBLIC RIGHT TO KNOW.—

(1) FACT SHEETS.—Any producer operating an establishment in any State shall prepare or obtain a fact sheet complying with this subsection for each active ingredient manufactured or used at the establishment. The producer shall maintain copies of the fact sheet at the establishment and shall furnish a copy to any person on request.

(2) CONTENTS.—

(A) Each fact sheet for an ingredient required under paragraph (1) shall—

(i) contain the chemical name, each common name, and any trade name of the ingredient and a summary of relevant health, safety, and environmental data concerning the ingredient; and

(ii) be revised as often as is necessary to reflect current information about the ingredient.

(B) The Administrator may require a fact sheet to be amended to provide accurate and clear information to the public.

(3) REPORTS.—Each producer to whom this subsection applies shall furnish to the Administrator annually, in accordance with regulations published by the Administrator, a report that includes—

(A) for each establishment operated by the producer in any State, the name of each ingredient for which a fact sheet is required that is manufactured or used at that establishment;

(B) for each ingredient for which a fact sheet is required, the location of each establishment where such ingredient is manufactured or used by the producer; and

(C) a current copy of each required fact sheet.

(4) PUBLIC AVAILABILITY.—The fact sheets required by paragraph (1) and the annual reports required by paragraph (3) shall be available to the public.

(f) INFORMATION REQUESTS.—Consistent with section 3507(a)(1) of title 44, United States Code, the Administrator shall catalog and retrieve data in such a manner as to eliminate or reduce burdensome

requests to registrants for submission of information, particularly requests that require the submission of duplicate confidential data.

[SEC. 8. BOOKS AND RECORDS.

[(a) REQUIREMENTS.—The Adminstrator may prescribe regulations requiring producers to maintain such records with respect to their operations and the pesticides and devices produced as he determines are necessary for the effective enforcement of this Act. No records required under this subsection shall extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data (other than data relating to registered pesticides or to a pesticide for which an application for registratin has been filed).

[(b) INSPECTION.—For the purposes of enforcing the provisions of this Act, any producer, distributor, carrier, dealer, or any other person who sells or offers for sale, delivers or offers for delivery any pesticide or device subject to this Act, shall upon request of any officer or employee of the Environmental Protection Agency or of any State or political subdivision, duly designated by the Adminsitrator, furnish or permit such person at all reasonable times to have access to, and to copy: (1) all records showing the delivery, movement or holding of such pesticide or device, including the quantity, the date of shipment and receipt, and the name of the consignor and consignee; or (2) in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery movement, or holding of the pesticide or device. Any inspection with respect to any records and information referred to in this subsection shall not extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed). Before undertaking an inspection under this subsection, the officer or employee must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, appropriate credentials and a written statement as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing. Each such inspection shall be commenced and completed with reasonable promptness.]

SEC. 8 RECORDS.

(a) AUTHORITY TO REQUIRE RECORDS.—

(1) IN GENERAL.—The Administrator, by regulation, may require any producer or exporter of a pesticide, registrant, applicant for registration, applicant for or holder of an experimental use permit, pesticide testing facility, commercial applicator, or any person who distributes or sells a pesticide, or any holder of a pesticide that is the subject of a regulation issued under section 19(b)—

(A) to prepare, and to maintin for reasonable periods of time, such records as the Administrator finds to be necessary for the effective implementation or enforcement of this Act;

(B) to furnish to the Administrator reports stating the location where the records are maintained; and

(C) to furnish a copy of any such record to the Administrator on written request.

(2) RETAIL DISTRIBUTION OR SALE.—Except as provided in subsections (c), (d), and (e), the Administrator may not require any person who distributes or sells at retail a registered pesticide that is not subject to a restricted use classification under section 3 to prepare, maintain or furnish any record under this subsection with respect to such pesticide.

(b) LIMITATIONS.—The Administrator may not, under the authority of subsection (a), require any person to maintain records of—

(1) financial data, sales data, or pricing data;

(2) personnel data, except for data concerning exposure of employees to pesticides or ingredients of pesticides, or concerning health effects on employees that could reasonably be attributable to such exposure; or

(3) research or test data other than—

(A) data relating to a registered pesticide;

(B) data relating to any pesticide for which an application for registration or for an experimental use permit has been filed;

(C) data relating to testing at a pesticide testing facility; or

(D) data relating to the storage or disposal of a pesticide whose registration has been suspended or canceled.

(c) RECORDS OF APPLICATORS.—

(1) COMMERCIAL APPLICATORS.—The Administrator shall require each commercial applicator to maintain records of each pesticide application, including the identity and quantity of pesticide applied and the date and location of such application, for a period of 2 years after each such application.

(2) PRIVATE APPLICATORS.—No regulations issued by the Administrator to carry out this Act may require any private applicator to maintain any records or file any reports or other documents.

(d) RECORDS OF PESTICIDE DEALERS.—

(1) IN GENERAL.—The Administrator, by regulation, shall require each pesticide dealer to maintain a record of each sale or distribution of—

(A) a pesticide classified for restricted use; and

(B) any other pesticide designated for purposes of this subsection by the Administrator by regulation because the pesticide may cause significant adverse effects on health or the environment.

(2) CONTENTS.—Such records shall include the identity of the pesticide sold or distributed, the identity of the person to whom the pesticide was distributed or sold, the date of the distribution or sale, and the amount of the pesticide distributed or sold.

(3) DURATION.—A pesticide dealer shall maintain the records required under this subsection for 3 years after the date of the distribution or sale.

(e) ACCESS.—

(1) EMPLOYEES, CUSTOMERS, AND COMPLAINANTS.—

(A) A pesticide dealer or commercial applicator shall afford to an employee or former employee of such dealer or applicator access to records required to be kept under subsections (c) and (d) that directly relate to the employment duties of the employee.

(B) A pesticide dealer or commercial applicator shall afford to a customer of such dealer or applicator access to the records that directly relate to any pesticide that the customer purchased from the dealer or that relate to any pesticide application made by such an applicator at the request of the customer or under a contract with a customer.

(C) Each State enforcement agency, as part of an investigation or enforcement action in response to a formal complaint, shall make available reports of the findings of such investigation or action to the complainant. On the request of a complainant, such agency shall provide in a timely manner a progress report or interim report that contains, at a minimum, the records required to be kept under subsections (c) and (d) and obtained in the investigation or action.

(D) The records for which access is provided under subparagraph (A), (B), or (C) shall be accessible within 30 days after a request made under such subparagraph, except that if necessary to protect the public health or in a medical emergency, such records shall be provided as soon as possible, but no later than 24 hours, after the request is made.

(2) STATE AGENCIES.—A copy of any record to be required to be maintained under subsection (c) or (d) shall be submitted to a State agency that has primary enforcement authority under section 26 on request by such State agency to the commercial applicator or dealer required to maintain such records.

(f) INFORMATION FOR EMPLOYEES.—An employer who uses or supervises the use of a pesticide shall—

(1) know or have access to the brand name and common or chemical name of each ingredient listed on the labeling of the pesticide, and to the safety, first aid, and antidote information listed on the labeling of the pesticide; and

(2) be responsible for promptly making such information available, on request, to any employee exposed to the pesticide and to treating medical personnel.

(g) DEFINITION OF PESTICIDE DEALER.—As used in this section, the term "pesticide dealer" means any person who, in the ordinary course of business, distributes or sells any pesticide that is classified for restricted use or designated under subsection (d).

SEC. 9. INSPECTION OF ESTABLISHMENTS, ETC.

[(a) IN GENERAL.—For purposes of enforcing the provisions of this Act, officers or employees duly designated by the Administrator are authorized to enter at reasonable times, any establishment or other place where pesticides or devices are held for distribution or sale for the purpose of inspecting and obtaining samples of any pesticides or devices, packaged, labeled, and released for shipment, and sample of any containers or labeling for such pesticides or devices.

[Before undertaking such inspection, the officers or employees must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, appropriate credentials and a written statement as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing. Each such inspection shall be commenced and completed with reasonable promptness. If the officer or employee obtains any samples, prior to leaving the premises, he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained and, if requested, a portion of each such sample equal in volume or weight to the portion retained. If an analysis is made of such samples, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

[(b) WARRANTS.—For purposes of enforcing the provisions of this Act and upon a showing to an officer or court of competent jurisdiction that there is reason to believe that the provisions of this Act have been violated, officers or employees duly designated by the Administrator are empowered to obtain and to execute warrants authorizing—

[(1) entry for the purpose of this section;

[(2) inspection and reproduction of all records showing the quantity, date of shipment, and the name of consignor and consignee of any pesticide or device found in the establishment which is adulterated, misbranded, not registered (in the case of a pesticide) or otherwise in violation of this Act and in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement, or holding of the pesticide or device; and

[(3) the seizure of any pesticide or device which is in violation of this Act.]

(a) AUTHORITY TO ENTER, INSPECT, AND COPY.—An officer or employee of the United States or of any State, duly designated by the Administrator, is authorized at reasonable times, as provided by this section—

(1) to enter any place where any pesticide, active ingredient, or device is distributed or sold, to inspect and obtain samples of any pesticide, active ingredient, or device being distributed or sold at such place or of any packaging or labeling of any such pesticide, active ingredient, or device;

(2) in the case of a pesticide the registration of which has been canceled or suspended under section 6, to enter any place in which the pesticide is stored or held in order to inspect and obtain samples of the pesticide or of any packaging or labeling of the pesticide, and to inspect the manner in which the pesticide is being stored or held;

(3) to enter any place where there are located any records required under this Act or any place reported under section 8(a) as a location where such records are maintained, to inspect and obtain copies of such records;

(4) to enter any pesticide testing facility—

(A) to inspect the facility and the testing being conducted at the facility; and

(B) to inspect and obtain copies of any records required by or under the authority of this Act to be maintained by the pesticide testing facility; and

(5) to enter any place where such officer or employee has reason to believe that this Act has been or is being violated by any person other than a person acting in the capacity of a private applicator, to inspect such place to obtain evidence of such violation.

(b) WARRANTS.—An officer or employee of the United States or of any State, duly designated by the Administrator, is empowered to obtain and execute warrants authorizing—

(1) entry, inspection, and obtaining of evidence for the purposes of this section;

(2) inspection and copying of all records required under this Act; and

(3) seizure of any pesticide, device, active ingredient, labeling, or packaging that is in violation of this Act.

(c) ENFORCEMENT.—

(1) CERTIFICATION OF FACTS TO ATTORNEY GENERAL.—The * * *

* * * * * * *

(d) PROCEDURE.—

(1) CREDENTIALS AND STATEMENTS.—Before any entry or inspection of any premises not open to the general public is made under this section, the person conducting the inspection shall present to the person in charge of the premises appropriate credentials, and a written statement of the reason for the entry or inspection and whether a violation of this Act is suspected.

(2) PROMPTNESS.—Each entry or inspection shall be commenced and completed with reasonable promptness.

(3) SAMPLES.—If the person conducting the entry or inspection obtains a sample of a pesticide or device, before leaving the premises such person shall give to the person in charge of the premises a receipt describing the sample and, if requested and practicable, a portion of each such sample equal in volume or weight to the portion retained. If an analysis of any such sample is made, a copy of the results of such analysis shall be furnished on request to the person in charge of the premises.

(e) COORDINATION.—The Administrator shall coordinate actions taken under this section with actions taken under other Federal laws for the purpose of avoiding duplication of inspections.

(f) CRIMINAL VIOLATIONS.—An officer or employee of the United States or of any State, duly designated by the Attorney General, may obtain and execute a warrant in accordance with rule 41 of the Federal Rules of Criminal Procedure if a court or magistrate determines under such rule that there is probable cause to believe that—

(1) a criminal violation of this Act has occurred or is occurring on the property to be entered or searched; or

(2) evidence of a criminal violation of this Act will be found on such property.

SEC. 10. PROTECTION OF TRADE SECRETS AND OTHER INFORMATION.

(a) GENERAL.—In * * *

* * * * * * *

(d) LIMITATIONS.—

(1) All information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide or any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public[: *Provided,* That the]. *The* use of such data for any registration purpose shall be governed by section 3 of this Act[: *Provided further,* That this]. *This* paragraph does not authorize the disclosure of any information that—

(A) discloses manufacturing or quality control process,

(B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or

(C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide.

unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.

(2) Information concerning production, distribution, sale, or inventories of a pesticide that is otherwise entitled to confidential treatment under subsection (b) of this section may be publicly disclosed in connection with a public proceeding to determine whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment, if the Administrator determines that such disclosure is necessary in the public interest.

(3) [If] *Except with respect to disclosure of information on inert ingredients in ingredient statements in accordance with section 2(n), if* the Administrator proposes to disclose information described in clause (A), (B), or (C) of paragraph (1) or in paragraph (2) of this subsection, the Administrator shall notify by certified mail the submitter of such information of the intent to release such information. The Administrator may not release such information, without the submitter's consent, until thirty days after the submitter has been furnished such notice[: *Provided,* That where]. *Where* the Administrator finds that disclosure of information described in clause (A), (B), or (C) of paragraph (1) of this subsection is necessary to avoid or lessen an imminent and substantial risk of injury to the public health, the Administrator may set such shorter period of notice (but not less than ten days) and such method of notice as the Administrator finds appropriate. During such period the data submitter may institute an action in an appropriate district court to enjoin or limit the proposed disclosure. The court

may enjoin disclosure, or limit the disclosure or the parties to whom disclosure shall be made, to the extent that—

(A) in the case of information described in clause (A), (B), or (C) of paragraph (1) of this subsection, the proposed disclosure is not required to protect against an unreasonable risk of injury to health or the environment; or

(B) in the case of information described in paragraph (2) of this subsection, the public interest in availability of the information in the public proceeding does not outweigh the interests in preserving the confidentiality of the information.

* * * * * * *

(h) DATA DISCLOSURE TO STATES.—

(1) IN GENERAL.—The Administrator may disclose to a State any data or information acquired under this Act if the State assures the Administrator, and the Administrator determines, that the submitter of the data or information will receive no less protection with respect to the disclosure and use of the data or information by the State than is provided by section 3 and this section.

(2) ACTION FOR JUST COMPENSATION.—For the purpose of any action that may lie against the United States for just compensation under section 1491 of title 28, United States Code—

(A) the disclosure or use of data or information provided by the Administrator under paragraph (1) to a State in a manner inconsistent with this section or section 3 shall be considered a taking of property; and

(B) the act of a State with respect to such data or information shall be considered an act of the United States.

(3) REQUIRED DISCLOSURE.—The Administrator shall disclose to a State any data or information acquired under this Act if the State assures the Administrator, and the Administrator determines, that—

(A) the submitter of the data or information will receive no less protection with respect to the disclosure and use of the data or information by the State than if provided by section 3 and this section; and

(B) the law of the State allows the submitter of the data or information to recover just compensation in a civil action against the State for losses resulting from the disclosure or use of the data or information by the State or its employees or agents in a manner inconsistent with section 3 or this section.

[SEC. 11. STANDARDS APPLICABLE TO PESTICIDE APPLICATORS.

[(a) IN GENERAL.—No regulations prescribed by the Administrator for carrying out the provisions of this Act shall require any private applicator to maintain any records or file any reports or other documents.

[(b) SEPARATE STANDARDS.—When establishing or approving standards for licensing or certification, the Administrator shall establish separate standards for commercial and private applicators.]

SEC. [4.] *11.* USE OF RESTRICTED USE PESTICIDES; CERTIFIED APPLICATORS.

(a) CERTIFICATION PROCEDURE.—

(1) FEDERAL CERTIFICATION.—In any State for which a State plan for applicator certification has not been approved by the Administrator, the Administrator, in consultation with the Governor of such State, shall conduct a program for the certification of applicators of pesticides[: *Provided,* That such]. *Such* program shall conform to the requirements imposed upon the States under the provisions of subsection (a)(2) of this section and shall not require private applicators to take any examination to establish competency in the use of pesticides. Prior to the implementation of the program, the Administrator shall publish in the Federal Register for review and comment a summary of the Federal plan for applicator certification and shall make generally available within the State copies of the plan. The Administrator shall hold public hearings at one or more locations within the State if so requested by the Governor of such State during the thirty days following publication of the Federal Register notice inviting comment on the Federal plan. The hearings shall be held within thirty days following receipt of the request from the Governor. In any State in which the Administrator conducts a certification program, the Administrator may require any person engaging in the commercial application, sale, offering for sale, holding for sale, or distribution of any pesticide one or more uses of which have been classified for restricted use to maintain such records and submit such reports concerning the commercial application, sale, or distribution of such pesticide as the Administrator may by regulation prescribe. Subject to paragraph (2), the Administrator shall prescribe standards for the certification of applicators of pesticides. Such standards shall provide that to be certified, an individual must be determined to be competent with respect to the use and handling of pesticides, or to the use and handling of the pesticide or class of pesticides covered by such individual's certification[: *Provided, however,* That the]. *The* certification standard for a private applicator shall, under a State plan submitted for approval, be deemed fulfilled by his completing a certification form. The Administrator shall further assure that such form contains adequate information and affirmations to carry out the intent of this Act, and may include in the form an affirmation that the private applicator has completed a training program approved by the Administrator so long as the program does not require the private applicator to take, pursuant to a requirement prescribed by the Administrator, any examination to establish competency in the use of the pesticide. The Administrator may *by regulation* require any pesticide dealer participating in a certification program to be licensed under a State licensing program approved by him.

* * * * * * *

(d) USE BY COMMERCIAL APPLICATORS.—

(1) IN GENERAL.—It shall be a violation of this Act for any person to use any pesticide as a commercial applicator unless such person is—

(A) a certified commercial applicator; or

(B) a registered commercial applicator under the direct supervision of a certified commercial applicator.

(2) CERTIFIED COMMERCIAL APPLICATORS.—To be considered to be a certified commercial applicator, a person, at a minimum, shall—

(A) have met the standards prescribed under subsection (a) and have received training—

(i) prescribed by the State agency, including training in the material referred to in subsection (g);

(ii) conducted by a trainer who has met the requirements prescribed under subsection (h); and

(iii) that satisfies the minimum standards for training programs prescribed under subsection (h);

(B) have had field, institutional, or industrial experience in pesticide use and application;

(C) have passed an examination prescribed by such State agency; and

(D) possess a valid commercial applicator certification issued by such State agency.

(3) REGISTERED COMMERCIAL APPLICATORS.—

(A) To be considered to be a registered commercial applicator, a person, at a minimum, shall—

(i) have received training—

(I) prescribed by the State agency, including training in the material referred to in subsection (g); and

(II) conducted by a trainer who has met the requirements prescribed under subsection (h); and

(ii) possess a valid registration issued by such State agency.

(B) A person may obtain a registration by providing to the State agency a report, signed and dated by the trainer and by the person who received the training, stating that the prescribed minimum training has been provided and received.

(e) USE BY PRIVATE APPLICATORS.—

(1) IN GENERAL.—A restricted use pesticide shall be considered to have been applied by, or under the direct supervision of, a certified private applicator only if the pesticide is applied by a person who is either—

(A) a certified private applicator; or

(B) a supervised private applicator who uses the pesticide under the direct supervision of a certified private applicator.

(2) CERTIFIED PRIVATE APPLICATORS.—To be considered to be a certified private applicator, a person, at a minimum, shall—

(A) have met the standards prescribed under subsection (a) and have received training—

(i) prescribed by the State agency, including training in the material described in subsection (g);

(ii) conducted by a trainer who has met the requirements prescribed under subsection (h); and

(iii) that satisfies the minimum standards for training prescribed under subsection (h); and

(B) possess a valid private applicator certification issued by such State agency.

(3) SUPERVISED PRIVATE APPLICATORS.—

(A) To be considered to be a supervised private applicator, a person, at a minimum, shall have received basic instruction—

(i) prescribed by the State agency or based on material prescribed by such State agency, including basic instruction material concerning the use of appropriate pesticide application, and safety procedures, appropriate clothing and protective equipment for pesticide applications, the detection of common symptoms of pesticide poisoning, the means of obtaining emergency medical treatment, hazards posed by pesticides to workers, the public health, and the environment, and the requirements of applicable laws, regulations, and labeling; and

(ii) given by a certified private applicator, a commercial applicator who is certified in the pest control category appropriate for the instruction being provided, or a trainer who has met the requirements prescribed under subsection (h).

(B) The State agency may require the employer of a supervised private applicator to confirm that the basic instruction described in subparagraph (A)(i) has been received.

(f) RECERTIFICATION AND REREGISTRATION.—

(1) IN GENERAL.—Each certified applicator and each registered commercial applicator within a State shall undergo refresher training and be recertified or reregistered within a period established by the State agency of such State of not more than 5 years.

(2) TRAINING MATERIAL.—The refresher training shall be prescribed by the State agency and shall include training in the materials referred to in subsection (g) and in the relevant requirements of other subsections of this section and sections 3(d), 12, and 14.

(3) RECERTIFICATION.—To be recertified, an applicator, at a minimum, shall meet—

(A) the requirements of subparagraphs (A), (B), and (D) of subsection (d)(2); or

(B) the requirements of paragraphs (1) and (2) of subsection (e).

(4) REREGISTRATION.—To be reregistered, a commercial applicator, at a minimum, shall meet the requirements of subsection (d)(3).

(g) TRAINING MATERIAL.—

(1) DEVELOPMENT.—The Administrator, in consultation with the Secretary of Agriculture, shall develop training material on the use of appropriate procedures for the application of pesticides, safety procedures for pesticide application, clothing, and

protective equipment for pesticide application, the detection of common symptoms of pesticide poisoning, the means of obtaining emergency medical treatment, hazards posed by pesticides to workers, the public health, and the environment, specific commercial application categories, and the requirements of applicable laws, regulations, and labeling.

(2) REVISIONS.—Within 12 months after the effective date of this section, the Administrator, in consultation with the Secretary of Agriculture, shall revise and make current such material and thereafter shall update such material as needed.

(h) MINIMUM STANDARDS FOR TRAINERS AND TRAINING PROGRAMS.—

(1) TRAINING OF COMMERCIAL APPLICATORS.—

(A) The Administrator shall establish within 1 year after the effective date of this section—

(i) minimum standards of competency, and experience or expertise, for trainers referred to in subsection (d); and

(ii) minimum standards for the training programs referred to in subsection (d).

(B) Training programs prescribed by any State under subsection (d) shall comply with the minimum standards established by the Administrator under subparagraph (A) not later than 2 years after the effective date of such standards. If on the expiration of such 2-year period a State's training program fails to meet such minimum standards, or if a State fails to prescribe such a program, the Administrator shall notify the State of such failure. After receipt of a notice, a State shall have 90 days to bring the training program of the State into compliance with such standards. If on expiration of such 90-day period, the training program of the State does not meet such standards, the Administrator shall prescribe such training programs referred to in subsection (d) for use in such State.

(2) TRAINING OF PRIVATE APPLICATORS.—

(A) The Administrator shall establish within 2 years after the effective date of this section—

(i) minimum standards of competency, and experience or expertise, for trainers referred to in subsection (e); and

(ii) minimum standards for the training programs referred to in subsection (e).

(B) Training programs prescribed by any State under subsection (e) shall comply with the minimum standards established by the Administrator under subparagraph (A) not later than 2 years after the effective date of such standards. If on the expiration of such 2-year period the training program of a State fails to meet such minimum standards, or if a State fails to prescribe such a program, the Administration shall notify the State of such failure. After receipt of a notice, a State shall have 90 days to bring the training program of the State into compliance with such standards. If on expiration of such 90-day period the training program of the State does not meet such standards, the Administra-

tor shall prescribe the training programs referred to in subsection (e) for use in such State.

(i) PRIVATELY ADMINISTERED TRAINING PROGRAMS.—A State agency may approve any privately administered training program that the Administrator determines meets the more stringent of—

(1) requirements established under this section; or

(2) requirements established by the State agency.

(j) ENFORCEMENT OFFICER TRAINING.—Federal and State field personnel responsible for on-site observations and inspections of pesticide use shall have training that, at a minimum, includes training covering materials specified in subsection (g) for the commercial application categories for which they are assigned enforcement responsibility.

(k) SEPARATE STANDARDS.—In establishing standards under this section applicable to applicators, the Administrator shall establish separate standards for commercial applicators and private applicators.

(l) DEFINITION OF STATE AGENCY.—For purposes of this section, the term "State agency" means the agency of a State that is designated under subsection (a)(2)(A) if the State has primary enforcement responsibility for pesticide use violations, as provided for by section 26. In the case of a State that does not have such primary enforcement responsibility or that does not have an agency designated under subsection (a)(2)(A), a reference to a State agency shall be considered a reference to the Administrator.

SEC. 12. UNLAWFUL ACTS.

(a) IN GENERAL.—

(1) Except as provided by subsection (b), it shall be unlawful for any person in any State to [distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person—] *distribute or sell to any person—*

[(A) any pesticide that is not registered under section 3, except as provided by section 6(a)(1);]

(A) any pesticide that is not registered under section 3 or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this Act;

[(B) any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 3;]

(B) to refuse to—

(i) prepare, maintain, or submit any records required by or under this Act;

(ii) submit any reports required by or under this Act; or

(iii) allow any entry, inspection, copying of records, or sampling authorized by this Act;

* * * * * * *

(F) [to make] *to distribute or sell, or to make* available for use, or to use, any registered pesticide classified for restricted use for some or all purposes other than in accord-

ance with section 3(d) and any regulations thereunder[: *Provided,* That it]. It shall not be unlawful to sell, under regulations issued by the Administrator, a restricted use pesticide to a person who is not a certified applicator for application by a certified applicator;

(G) to use * * *

(H) to use * * *

(I) to violate * * *

[(J) to violate any suspension order issued under section 6;

[(K) to violate any cancellation or registration of a pesticide under section 6, except as provided by section 6(a)(1);]

(J) to violate any suspension order issued under section 3(c)(2)(B), [*3A*]*4, or 6;*

(K) to violate any cancellation order issued under this Act or to fail to submit a notice in accordance with section 6(i);

(L) who is * * *

(M) to knowingly falsify all or part of any application for registration, application for experimental use permit, any information submitted to the Administrator pursuant to section 7, any records required to be maintained pursuant to [section 8] *this Act,* any report filed under this Act, or any information marked as confidential and submitted to the Administrator under any provision of this Act;

(N) who * * *

(O) to add any substance to, or take any substance from, any pesticide in a manner that may defeat the purpose of this Act; [or]

(P) to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test[.];

(Q) to obtain or use records acquired under section 8(e) in furtherance of a commercial purpose;

(R) to falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed, submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by this Act;

(S) to submit to the Administrator data known to be false in support of a registration;

(T) to violate any regulation issued under section 3(a), 19, 25(c)(3), or 25(f); or

(U) to violate an order issued under section 31(f)(2).

(b) EXEMPTIONS.—The * * *

* * * * * * *

(c) ACTS OF OFFICERS, AGENTS, ETC.—When constructing and enforcing the provisions of this Act, the act, omission, or failure of any officer, employee, agent, or other person acting for or employed by any person shall be deemed to be the act, omission, or failure of such person as well as that of the person employed.

SEC. 13. STOP SALE, USE, REMOVAL, AND SEIZURE.

(a) STOP SALE, ETC., ORDERS.—Whenever * * *

(b) SEIZURE.—Any pesticide or device that is being transported or, having been transported, remains unsold or in original unbroken packages, or that is sold or offered for sale in any State, or that is imported from a foreign country, shall be liable to be proceeded against in any district court in the district where it is found and seized for confiscation by a process in rem for condemnation if—

(1) in the case of a pesticide—

(A) it is adulterated or misbranded;

(B) it is not registered pursuant to the provisions of section 3;

(C) its labeling fails to bear the information required by this Act;

(D) it is not colored or discolored and such coloring or discoloring is required under this Act; or

(E) any of the claims made for it or any of the directions for its use differ in substance from the representations made in connection with its registration;

(2) in the case of a device, it is misbranded; or

(3) in the case of a pesticide or device, when used in accordance with the requirements imposed under this Act and as directed by the labeling, it nevertheless causes unreasonable adverse effects on the environment.

In the case of a plant regulator, defoliant, or desiccant, used in accordance with the label claims and recommendations, physical or physiological effects on plants or parts thereof shall not be deemed to be injury, which such effects are the purpose for which the plant regulator, defoliant, or desiccant was applied.

(c) DISPOSITION AFTER CONDEMNATION.—If the pesticide or device is condemned it shall, after entry of the decree, be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs, shall be paid into the Treasury of the United States, but the pesticide or device shall not be sold contrary to the provisions of this Act or the laws of the jurisdiction in which it is sold[: *Provided,* That upon]. *On* payment of the costs of the condemnation proceedings and the execution and delivery of a good and sufficient bond conditioned that the pesticide or device shall not be sold or otherwise disposed of contrary to the provision of the Act or the laws of any jurisdiction in which sold, the court may direct that such pesticide or device be delivered to the owner thereof. The proceedings of such condemnation cases shall conform, as near as may be to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

* * * * * * *

SEC. 14. PENALTIES.

(a) CIVIL PENALTIES.—

[(1) IN GENERAL.—Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than $5,000 for each offense.

[(2) PRIVATE APPLICATOR.—Any private applicator or other person not included in paragraph (1) who vilolates any provision of this Act subsequent to receiving a written warning from the Administrator or following a citation for a prior violation, may be assessed a civil penalty by the Administrator of not more than $1,000 for each offense: *Provided,* That any applicator not included under paragraph (1) of this subsection who holds or applies registered pesticides or uses dilutions of registered pesticides, only to provide a service to controlling pests without delivering any unapplied pesticide to any person so served and who violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than $500 for the first offense nor more than $1,000 for each subsequent offense.]

(1) IN GENERAL.—

"(A) Any person who is (or who is acting for or employed by) a registrant, applicant for registration, producer, or pesticide testing facility, or a holder of a pesticide that is subject to a regulation under section 19(b), that violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than $25,000 for each offense. If such a person violates any provision of this Act after violating the same or similar provision of this Act, the Administrator may assess a civil penalty of not more than $50,000 for such subsequent violation.

(B) Any—

(i) commercial applicator of restricted use pesticides; or

(ii) any other person not described in subparagraph (A) who distributes or sells pesticides or devices,

that violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than $10,000 for each offense. If such person violates any provision of this Act after violating the same or similar provision of this Act, the Administrator may assess a civil penalty of not more than $20,000 for such subsequent violation.

(2) PRIVATE APPLICATOR.—Any private applicator who violates any provision of this Act subsequent to receiving a written warning from the Administrator or following a citation for a prior violation, and any other person not included in paragraph (1) that violates any provision of this Act, may be assessed a civil penalty by the Administrator of not more than $1,000 for each offense. If such person violates any provision of this Act after violating the same or similar provision of this Act, the Administrator may assess a civil penalty of not more than $2,000 for such subsequent violation. The Administrator may waive the requirements for a warning or citation for a first offense by a private applicator if the Administrator determines

that the violation was intentional or caused (or had the potential to cause) significant harm to health or the environment.]

(3) HEARING.—No civil penalty shall be assessed unless the person charged shall have been given notice and opportunity for a hearing on such charge in the county, parish, or incorporated city of the residence of the person charged. *If the person neither resides nor has a principal place of business in the United States, the Administrator may designate a site for the hearing in the United States that is reasonably convenient for the parties.*

(4) DETERMINATION OF PENALTY.—In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, *the economic benefit (if any) resulting from the violation,* and the gravity of the violation. Whenever the Administrator finds that the violation occurred despite the exercise of due care or did not cause significant harm to health or the environment, the Administrator may issue a warning in lieu of assessing a penalty.

(5) REFERENCES TO ATTORNEY GENERAL.—In * * *

(6) SUBPOENAS.—The Administrator, in connection with administrative proceedings under this subsection, may issue subpoenas compelling the attendance and testimony of witnesses and subpoenas duces tecum and may request the Attorney General to bring an action to enforce any subpoena issued under this paragraph. The district courts of the United States shall have jurisdiction to enforce such subpoenas and impose sanctions.

(b) CRIMINAL PENALTIES.—

[(1) IN GENERAL.—Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who knowingly violates any provision of this Act shall be guilty of a misdemeanor and shall on conviction be fined not more than $25,000, or imprisoned for not more than one year, or both.]

(1) IN GENERAL.—

(A) Any person who is (or who is acting for or employed by) a registrant, applicant for a registration, producer, or pesticide testing facility, or a holder of a pesticide that is subject to a regulation under section 19(b), that knowingly violates any provision of this Act shall be fined not more than $50,000 or imprisoned for not more than 2 years, or both.

(B) Any commercial applicator of a restricted use pesticide, or any other person not described in subparagraph (A) who distributes or sells pesticides or devices, that knowingly violates any provision of this Act shall be fined not more than $25,000 or imprisoned for not more than 1 year, or both.

(2) PRIVATE APPLICATOR.—Any private applicator or other person not included in paragraph (1) who knowingly violates any provision of this Act shall be guilty of a misdemeanor and shall on conviction be fined not more than [$1,000], *$2,000* or imprisoned for not more than [30] *60* days, or both.

[(3) DISCLOSURE OF INFORMATION.—Any person, who, with intent to defraud, uses or reveals information relative to formulas of products acquired under the authority of section 3, shall be fined not more than $10,000, or imprisoned for not more than three years, or both.]

(3) DISCLOSURE OF INFORMATION.—

(A) Any person who, with intent to defraud, uses or reveals information relative to the formula of a product acquired under section 3 shall be fined not more than $25,000 or imprisoned for not more than 3 years, or both.

(B) Any person, including any officer, contractor, or employee of the United States or a State, who—

(i) is granted access to data under section 3(c)(9); and

(ii) in furtherance of a commercial purpose involving the production, registration, distribution, or sale of a pesticide—

(I) knowingly violates such section; or

(II) knowingly allows data to be made available in violation of such section,

shall be fined not more than $100,000 or imprisoned for not more than 3 years, or both.

[(4) ACTS OF OFFICERS, AGENTS, ETC.—When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any person shall in every case be also deemed to be the act, omission, or failure of such person as well as that of the person employed.]

[SEC. 15. INDEMNITIES.

[(a) REQUIREMENT.—If—

[(1) the Administrator notifies a registrant that he has suspended the registration of a pesticide because such action is necessary to prevent an imminent hazard;

[(2) the registration of the pesticide is canceled as a result of a final determination that the use of such pesticide will create an imminent hazard; and

[(3) any person who owned any quantity of such pesticide immediately before the notice to the registrant under paragraph (1) suffered losses by reason of suspension or cancellation of the registration,

the Administrator shall make an indemnity payment to such person, unless the Administrator finds that such person [(i)] had knowledge of facts which, in themselves, would have shown that such pesticide did not meet the requirements of section 3(c)(5) for registration, and [(ii)] continued thereafter to produce such pesticide without giving timely notice of such facts to the Administrator.

[(b) AMOUNT OF PAYMENT.—

[(1) IN GENERAL.—The amount of the indemnity payment under subsection (a) to any person shall be determined on the basis of the cost of the pesticide owned by such person immediately before the notice to the registrant referred to in subsection (a)(1); except that in no event shall an indemnity payment to any person exceed the fair market value of the pesticide

owned by such person immediately before the notice referred to in subsection (a)(1).

[(2) SPECIAL RULE.—Notwithstanding any other provision of this Act, the Administrator may provide a reasonable time for use or other disposal of such pesticide. In determining the quantity of any pesticide for which indemnity shall be paid under this subsection, proper adjustment shall be made for any pesticide used or otherwise disposed of by such owner.]

SEC. 15. INDEMNITIES.

(a) GENERAL INDEMNIFICATION.—

(1) IN GENERAL.—Except as otherwise provided in this section, if—

(A) the Administrator notifies a registrant under section 6(c)(1) that the Administrator intends to suspend a registration or that an emergency order of suspension of a registration under section 6(c)(3) has been issued;

(B) the registration in question is suspended under section 6(c), and thereafter is canceled under section 6(b), 6(d), or 6(g); and

(C) any person who owned any quantity of the pesticide immediately before the notice to the registrant under subparagraph (A) suffered losses by reason of suspension or cancellation of the registration;

the Administrator shall make an indemnity payment to the person.

(2) EXCEPTION.—Paragraph (1) shall not apply if the Administrator finds that the person—

(A) had knowledge of facts that, in themselves, would have shown that the pesticide did not meet the requirements of section 3(c)(5) for registration; and

(B) continued thereafter to produce the pesticide without giving timely notice of such facts to the Administrator.

(3) REPORT.—If the Administrator takes an action under paragraph (1) that requires the payment of indemnification, the Administrator shall report to the Committee on Agriculture of the House of Representatives, the Committee on Agriculture, Nutrition, and Forestry of the Senate, and the Committees on Appropriations of the House of Representatives and the Senate on—

(A) the action taken that requires the payment of indemnification;

(B) the reasons for taking the action;

(C) the estimated cost of the payment; and

(D) a request for the appropriation of funds for the payment.

(4) APPROPRIATION.—The Administrator may not make a payment of indemnification under paragraph (1) unless a specific line item appropriation of funds has been made in advance for the payment.

(b) INDEMNIFICATION OF END USERS, DEALERS, AND DISTRIBUTORS.—

(1) END USERS.—If—

(A) the Administrator notifies a registrant under section 6(c)(1) that the Administrator intends to suspend a registration or that an emergency order of suspension of a registration under section 6(c)(3) has been issued;

(B) the registration in question is suspended under section 6(c), and thereafter is canceled under section 6(b), 6(d), or 6(g); and

(C) any person who, immediately before the notice to the registrant under subparagraph (A), owned any quantity of the pesticide for purposes of applying or using the pesticide as an end user, rather than for purposes of distributing or selling it or further processing it for distribution or sale, suffered a loss by reason of the suspension or cancellation of the pesticide;

the person shall be entitled to an indemnity payment under this subsection for such quantity of the pesticide.

(2) DEALERS AND DISTRIBUTORS.—

(A) Any registrant, wholesaler, dealer, or other distributor (hereinafter in this paragraph referred to as a "seller") of a registered pesticide who distributes or sells the pesticide directly to any person not described as an end user in paragraph (1)(C) shall, with respect to any quantity of the pesticide that such person cannot use or resell as a result of the suspension or cancellation of the pesticide, reimburse such person for the cost of first acquiring the pesticide from the seller (other than the cost of transportation, if any), unless the seller provided to the person at the time of distribution or sale a notice, in writing, that the pesticide is not subject to reimbursement by the seller.

(B) If—

(i) the Administrator notifies a registrant under section 6(c)(1) that the Administrator intends to suspend a registration or that an emergency order of suspension of a registration under section 6(c)(3) has been issued;

(ii) the registration in question is suspended under section 6(c), and thereafter is canceled under section 6(b), 6(d), or 6(g);

(iii) any person who, immediately before the notice to the registrant under clause(i)—

(1) had not been notified in writing by the seller, as provided under subparagraph (A), that any quantity of the pesticide owned by such person is not subject to reimbursement by the seller in the event of or suspension cancellation of the pesticide; and

(II) owned any quantity of the pesticide for purposes of—

(aa) distribution or selling it; or

(bb) further processing it for distribution or sale directly to an end user;

suffered a loss by reason of the suspension or cancellation of the pesticide; and

(iv) the Administrator determines on the basis of a claim of loss submitted to the Adminstrator by the person, that the seller—

(I) did not provide the notice specified in subparagraph (A) to such person; and

(II) is and will continue to be unable to provide reimbursement to such person, as provided under subparagraph (A), for the loss referred to in clause (iii), as a result of the insolvency or bankruptcy of the seller and the seller's resulting inability to provide such reimbursement;

the person shall be entitled to an indemnity payment under this subsection for such quantity of the pesticide.

(C) If an idemnity payment is made by the United States under this paragraph, the United States shall be subrogated to any right that would otherwise be held under this paragraph by a seller who is unable to make a reimbursement in accordance with this paragraph with regard to reimbursements that otherwise would have been made by the seller.

(3) SOURCE.—Any payment required to be made under paragraph (1) or (2) shall be made from the appropriation provided under section 1304 of title 31, United States Code.

(4) ADMINISTRATIVE SETTLEMENT.—An administrative settlement of a claim for such indemnity may be made in accordance with the third paragraph of section 2414 of title 28, United States Code, and shall be regarded as if it were made under that section for purposes of section 1304 of title 31, United States Code.

(c) AMOUNT OF PAYMENT.—

(1) IN GENERAL.—The amount of an indemnity payment under subsection (a) or (b) to any person shall be determined on the basis of the cost of the pesticide owned by the person (other than the cost of transportation, if any) immediately before the issuance of the notice to the registrant referred to in subsection (a)(1)(A), (b)(1)(A), or (b)(2)(i), except that in no event shall an indemnity payment to any person exceed the fair market value of the pesticide owned by the person immediately before the issuance of the notice.

(2) SPECIAL RULE.—Notwithstanding any other provision of this Act, the Administrator may provide a reasonable time for use or other disposal of the pesticide. In determining the quantity of any pesticide for which indemnity shall be paid under this section, proper adujustment shall be made for any pesticide used or otherwise disposed of by the owner.

SEC. 15. INDEMNITIES.

(a) REQUIREMENTS.—If—

(1) the Administrator notifies a registrant that he has suspended the registration of a pesticide because such action is necessary to prevent an imminent hazard;

(2) the registration of the pesticide is canceled as a result of a final determination that the use of such pesticide will create an imminent hazard; and

(3) any person who owned any quantity of such pesticide immediately before the notice to the registrant under paragraph (1) suffered losses by reason of suspension or cancellation of the registration,

the Administrator shall make an indemnity payment to such person, unless the Administrator finds that such person [(i)] had knowledge of facts which, in themselves, would have shown that such pesticide did not meet the requirements of section 3(c)(5) for registration, and [(ii)] continued thereafter to produce such pesticide without giving timely notice of such facts to the Administrator.

(b) AMOUNT OF PAYMENT.—* * *

* * * * * * *

SEC. 16. ADMINISTRATIVE PROCEDURE; JUDICIAL REVIEW.

[(a) DISTRICT COURT REVIEW.—Except as is otherwise provided in this Act, Agency refusals to cancel or suspend registrations or change classifications not following a hearing and other final Agency actions not committed to Agency discretion by law are judicially reviewable in the district courts.]

(a) DISTRICT COURT REVIEW.—Except as otherwise provided in this Act, the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other final actions of the Administrator not committed to the discretion of the Administrator by law are judicially reviewable by the district courts of the United States.

* * * * * * *

(c) REVIEW OF REGULATIONS.—

(1) IN GENERAL.—

(A) Any regulation issued under this Act and first published in the Federal Register in final form after the effective date of this subsection shall be reviewable only as provided by this subsection. Any person may obtain judicial review of the regulation by filing a petition for review in the United States court of appeals for the circuit wherein the person resides or has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit. Any petition under this paragraph for review of a regulation shall be filed within 120 days after the date of promulgation of the regulation as designated by the Administrator in the Federal Register.

(B) Any refusal by the Administrator of a petition to modify or rescind a regulation issued under this Act shall be reviewable only as provided by this subsection. Any person may obtain judicial review of the refusal by filing a petition for review in the United States court of appeals for the circuit wherein the person resides or has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit. Any such petition for review of a refusal to modify or rescind a regulation shall be filed within 120 days after such refusal.

(C) The scope of review under subparagraph (A) or (B) shall be as specified in section 706 of title 5, United States

Code. The commencement of a proceeding under subparagraph (A) or (B), unless specifically ordered by the court to the contrary, shall not operate as a stay of the regulation.

(2) JUDICIAL REVIEW.—A regulation issued by the Administrator or a refusal by the Administrator of a petition to modify or rescind a regulation issued under this Act shall not be subject to judicial review—

(A) in any suspension, cancellation, or denial proceeding under this Act or in any appeal therefrom; or

(B) in any proceeding under section 13 or 14(a), or subsection (c), or in any appeal therefrom except on request of a person who, as an agricultural producer, is adversely affected by such action.

(3) STAYS.—If a person who is a party to a proceeding described in subpargraph (A) or (B) of paragraph (2) that is based on a regulation issued under this Act petitions the Administrator to modify or rescind such regulation, the application of such regulation in the proceeding shall be stayed until the Administrator issues a final decision on the petition.

(4) DEFINITION OF AGRICULTURAL PRODUCER.—As used in this subsection, the term "agricultural producer" means a nongovernmental producer of an agricultural commodity who—

(A) uses or supervises the use of any pesticide for the production of such commodity on property owned or rented by the producer or the employer of the producer; or

(B) without compensation other than the trading of personal services, assists another agricultural producer with the application of pesticides on the land of the producer.

SEC. 17. IMPORTS AND EXPORTS.

[(a) PESTICIDES AND DEVICES INTENDED FOR EXPORT.—Notwithstanding any other provision of this Act, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this Act—

[(1) when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to sections 2(p), 2(q)(1) (A), (C), (D), (E), (G), and (H), 2(q)(2) (A), (B), (C) (i) and (iii), and (D), 7, and 8 of this Act; and

[(2) in the case of any pesticide other than a pesticide registered under section 3 or sold under section 6(a)(1) of this Act, if, prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under this Act. A copy of that statement shall be transmitted to an appropriate official of the government of the importing country.]

(a) PESTICIDES AND DEVICES INTENDED FOR EXPORT.—

(1) VIOLATIONS.—Notwithstanding any other provision of this Act, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be considered in violation of this Act when prepared or

packed according to the specifications or directions of the foreign purchaser and the legal requirements of the country of import, except that producers and exporters of such pesticides and devices and active ingredients used in producing pesticides shall be subject to sections 2(p), 2(q)(1) (A), (C), (D), (E), (G), (H), and (I), 2(q)(2) (A), (B), (C)(i), (C)(iii), and (D), 7, and 8, and paragraphs (2), (3), and (4) of this subsection.

(2) EXPORT OF RESTRICTED USE OR UNREGISTERED PESTICIDES.—

(A) This paragraph applies to a pesticide, device, or active ingredient—

(i) for which a restricted use classification has become effective under section 3;

(ii) for which a cancellation or suspension has become effective under section 6;

(iii) the registration of which has been voluntarily withdrawn by the registrant; or

(iv) that is not registered under section 3 for any use.

(B) No pesticide, device, or active ingredient described in subparagraph (A) may be exported to any country of import by any person unless prior to the intended date of the first shipment of each calendar year of such pesticide to such country, such person has transmitted to the Administrator—

(i) the name of the pesticide and the common and chemical names of the active ingredient;

(ii) the name and address of the exporter;

(iii) the name and address of the foreign purchaser;

(iv) the approximate dates and quantities of shipments of such pesticide, device, or active ingredient to such country during the following calendar year;

(v) the manner of transport of such shipments; and

(vi) the ports of entry.

(C) The report required by subparagraph (B) shall contain a notarized certification that—

(i) the country of import is named in the list maintained by the Administrator pursuant to subparagraph (E) and that the pesticide, device, or active ingredient is approved for use in that country;

(ii) the exporter will not permit such shipment to leave the United States until the Administrator has received written evidence that the notification required by subparagraph (D) was delivered to the appropriate government regulatory office in the country of import;

(iii) the pesticide, device, or active ingredient is manufactured, processed, packaged, and held in conformity with standards for composition and quality of the country of import, the World Health Organization, and the Food and Agriculture Organization and is not adulterated or misbranded;

(iv) the outside of the shipping package will be prominently labeled with the following statement: "This pesticide may be sold or offered for sale only in the following countries: ," the blank space being

filled with a list of the countries to which export of the pesticide, device, or active ingredient is authorized under this paragraph;

(v) in the case of a pesticide, device, or active ingredient referred to in clause (ii), (iii), or (iv) of subparagraph (A), that the outside of the shipping package will be conspicuously labeled with the following statement: "Not registered for use in the United States of America" in the official language of the country of import and appropriate local languages; and

(vi) the exporter will notify the Administrator of any changes in the information supplied pursuant to this subparagraph or subparagraph (B) after a shipment has left the United States, including in particular any diversion of such shipment to countries not named in the original information supplied to the Administrator.

(D) Not later than 30 days after the receipt of the report required by subparagraph (B), the Administrator shall notify the appropriate government regulatory office in the country of import. Such notification shall contain the following information in the official language or languages of the country of import—

(i) the information required by clauses (i) through (vi) of subparagraph (B);

(ii) a statement of the reasons why the pesticide, device, or active ingredient was canceled, suspended, voluntarily withdrawn, is not registered in the United States, or has been classified for restricted use, and the list of restrictions;

(iii) chemical and nonchemical alternatives to the pesticide, device or active ingredient; and

(iv) the name and address of the office of the United States Environmental Protection Agency that, on request by the importer or official of the country of import, can provide additional information on the pesticide.

Such notification shall request a written acknowledgment that the notification was delivered to the appropriate government regulatory office in the country of import. Within 30 days of receipt of the country of import's acknowledgement, the Administrator shall forward such acknowledgment to the exporter.

(E) The Administrator may compile a list of countries to which a pesticide, device, or active ingredient may be exported under this paragraph. Before adding a county to the list, the Administrator shall make a finding that each of the following criteria has been satisfied with respect to that country:

(i) The existence and effective operation of statutory or regulatory requirements that require the review of pesticides for human and environmental toxicity by an entity of the government of such country and that authorize the approval of only those pesticides that have been determined not to have unreasonable adverse ef-

fects on the environment or human health by experts independent of any pesticide manufacturer and employed by or acting on behalf of such entity, and qualified by scientific training and experience to evaluate the safety of pesticides.

(ii) The existence and effective operation of statutory or regulatory requirements that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of pesticides in the country are adequate to preserve their identity, quality, purity, and strength.

(iii) The existence and effective operation of statutory or regulatory requirements for withdrawing approval of and removing pesticides found not to be safe or effective.

(iv) The existence and effective operation of statutory or regulatory requirements that the labeling of pesticides must be in accordance with the terms of approval of the pesticide.

(v) The existence and effective operation of statutory or regulatory requirements for the collecting and recording of acute and chronic health effects and environmental effects.

(vi) The existence and effective operation of statutory or regulatory requirements for making health, safety, and environmental information available to workers and affected communities.

(vii) The existence and effective operation of statutory or regulatory requirements assuring the availability to workers and affected communities of training, protective equipment, and emergency procedures.

(viii) The existence and effective operation of statutory or regulatory requirements to assure that pesticide advertising encourages proper use, notifies of pesticide hazards, and is not misleading.

Additions or amendments to the list shall be made by regulation with a minimum 90-day period for public comment. The Administrator shall give particular weight to comments from the public in the country concerned.

(G) Documents referred to in this paragraph shall be made available to the public on request.

(3) LABELS.—

(A) The label of pesticides intended for export from the United States shall be written in the official languages of the country of import and appropriate local languages.

(B) Except as provided in section 2(q)(1)(H), such label may not refer to compliance with the laws of the United States unless the label also contains or is accompanied by a description of the relevant requirements of such laws.

(4) CONFIDENTIAL BUSINESS INFORMATION.—No information required to be disclosed pursuant to this section may be withheld from a foreign government on the basis of a claim of trade secrecy or confidential business information. Where such information has been claimed confidential by the submitter, it shall

be accompanied when supplied to a foreign government by a statement to that effect and a request to the foreign government to preserve its confidential character.

[(b) CANCELLATION NOTICES FURNISHED TO FOREIGN GOVERNMENTS.—Whenever a registration or a cancellation or suspension of the registration of a pesticide becomes effective, or ceases to be effective, the Administrator shall transmit through the State Department notification thereof to the governments of other countries and to appropriate international agencies. Such notification shall, upon request, include all information related to the cancellation or suspension of the registration of the pesticide and information concerning other pesticides that are registered under section 3 of this Act and that could be used in lieu of such pesticide.]

(b) NOTICES OF REGULATORY ACTION FURNISHED TO FOREIGN GOVERNMENTS.—

(1) ISSUANCE.—The Administrator shall promptly transmit through the Secretary of State a notice, at such time as the action is taken and annually thereafter, to the appropriate governmental regulatory offices of other countries and to appropriate international agencies whenever—

(A) a registration, or a cancellation or suspension of the registration, of a pesticide becomes effective or ceases to be effective; or

(B) a pesticide is classified for restricted use.

(2) CONTENTS.—A notice transmitted under paragraph (1) shall include—

(A) the reasons for the regulatory action taken;

(B) in the case of a canceled or suspended registration of a pesticide, information concerning other pesticides that are registered under section 3 and that could be used in lieu of such pesticide; and

(C) the name and address of the office of the United States Environmental Protection Agency that, on request, can provide additional information on the pesticide.

(c) IMPORTATION OF PESTICIDES AND DEVICES.—The Secretary of the Treasury shall notify the Administrator of the arrival of pesticides and devices and shall deliver to the Administrator, upon his request, samples of pesticides or devices which are being imported into the United States, giving notice to the owner or consignee, who may appear before the Administrator and have the right to introduce testimony. If it appears from the examination of a sample that it is adulterated, or misbranded or otherwise violates the provisions set forth in this Act, or is otherwise injurious to health or the environment, the pesticide or device may be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any pesticide or device refused delivery which shall not be exported by the consignee within 90 days from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe[: *Provided*, That the]. *The* Secretary of the Treasury may delivery to the consignee such pesticide or device pending examination and decision in the matter on execution of bond for the amount of the full invoice value of such pesticide or device, together with the duty thereon, and on refusal to return such pesticide or device for any

cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shll forfeit the full amount of said bond[: *And provided further,* That all]. *All* charges for storage, cartage, and labor on pesticides or devices which are refused admission or delivery shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

[(d) COOPERATION IN INTERNATIONAL EFFORTS.—The Administrator shall, in cooperation with the Department of State and any other appropriate Federal agency, participate and cooperate in any international efforts to develop improved pesticide research and regulations.]

(d) COOPERATION IN INTERNATIONAL EFFORTS.—The Administrator shall—

(1) in cooperation with the Department of State, other appropriate Federal agencies, and non-governmental and international organizations, actively participate in international efforts to develop improved pesticide research and regulatory programs and improved strategies for sustainable agriculture, including integrated pest management,

(2) provide foreign countries with technical assistance to develop comprehensive pesticide regulatory programs,

(3) within 1 year of the effective date of this subsection, and every 3 years thereafter, conduct and publish a survey of all countries that import pesticides from United States exporters or from which the United States imports agricultural commodities, to—

(A) ascertain what procedures are in place in each country regarding registration, labeling, and training to ensure safe handling, transportation, application, and disposal of pesticides; and

(B) control residues on foods in order to meet tolerances established under United States law;

(4) within 1 year of the effective date of this subsection, convene, in cooperation with the Department of State, a meeting to be held in the United States under the auspices of the Organization for Economic Cooperation and Development, and to sponsor such other meetings as may be necessary, to actively encourage the members of the Organization to adopt a binding multilateral convention containing regulatory measures for exported pesticides at least as stringent as those in this Act; and

(5) report to Congress annually on the activities conducted to comply with this subsection and the results thereof.

(e) REGULATIONS.—The * * *

SEC. 18. EXEMPTION OF FEDERAL AND STATE AGENCIES.

The Administrator may, at his discretion, exempt any Federal or State agency from any provision of this Act if he determines that emergency conditions exist which require such exemption. The Administrator, in determining whether or not such emergency conditions exist, shall consult with the Secretary of Agriculture and the Governor of any State concerned if they request such determination.

[SEC. 19. DISPOSAL AND TRANSPORTATION.

[(a) PROCEDURES.—The Administrator shall, after consultation with other interested Federal agencies, establish procedures and regulations for the disposal or storage of packages and containers of pesticides and for disposal or storage of excess amounts of such pesticides, and accept at convenient locations for safe disposal a pesticide the registration of which is canceled under section 6(c) if requested by the owner of the pesticide.

[(b) ADVICE TO SECRETARY OF TRANSPORTATION.—The Administrator shall provide advice and assistance to the Secretary of Transportation with respect to his functions relating to the transportation of hazardous materials under the Department of Transportation Act (49 U.S.C. 1657), the Transportation of Explosives Act (18 U.S.C. 831–835), the Federal Aviation Act of 1958 (49 U.S.C. 1421–1430, 1472 H), and the Hazardous Cargo Act (46 U.S.C. 170, 375, 416).

[(c) PROVISIONS FOR UNUSED QUANTITIES.—Notification of cancellation of any pesticide shall include specific provisions for the disposal of the unused quantities of such pesticide.]

SEC. 19. STORAGE, DISPOSAL, TRANSPORTATION, AND RECALL.

(a) STORAGE, DISPOSAL, AND TRANSPORTATION.—

(1) DATA REQUIREMENTS AND REGISTRATION OF PESTICIDES.—The Administrator may require under section 3 or 6 that—

(A) the registrant or applicant for registration of a pesticide submit or cite data or information regarding methods for the safe storage and disposal of excess quantities of the pesticide to support the registration or continued registration of a pesticide;

(B) the labeling of a pesticide contain requirements and procedures for the transportation, storage, and disposal of the pesticide, any container of the pesticide, any rinsate containing the pesticide, or any other material used to contain or collect excess or spilled quantities of the pesticide; and

(C) the registrant of a pesticide provide evidence of sufficient financial and other resources to carry out a recall plan under subsection (b), and provide for the disposition of the pesticide, in the event of suspension and cancellation of the pesticide.

(2) PESTICIDES.—The Administrator may by regulation, or as part of an order issued under section 6 or an amendment to such an order—

(A) issue requirements and procedures to be followed by any person who stores or transports a pesticide the registration of which has been suspended or canceled;

(B) issue requirements and procedures to be followed by any person who disposes of stocks of a pesticide the registration of which has been suspended; and

(C) issue requirements and procedures for the disposal of any pesticide the registration of which has been canceled.

(3) CONTAINERS, RINSATES, AND OTHER MATERIALS.—The Administrator may by regulation, or as part of an order issued under section 6 or an amendment to such an order—

(A) issue requirements and procedures to be followed by any person who stores or transports any container of a pesticide the registration of which has been suspended or canceled, any rinsate containing the pesticide, or any other material used to contain or collect excess or spilled quantities of the pesticide;

(B) issue requirements and procedures to be followed by any person who disposes of stocks of any container of a pesticide the registration of which has been suspended, any rinsate containing the pesticide, or any other material used to contain or collect excess or spilled quantities of the pesticide; and

(C) issue requirements and procedures for the disposal of any container of a pesticide the registration of which has been canceled, any rinsate containing the pesticide, or any other material used to contain or collect excess or spilled quantities of the pesticide.

(b) RECALLS.—

(1) IN GENERAL.—If the registration of a pesticide has been suspended and canceled under section 6, and if the Administrator finds that recall of the pesticide is necessary to protect health or the environment, the Administrator shall order a recall of the pesticide in accordance with this subsection.

(2) VOLUNTARY RECALL.—If, after determining under paragraph (1) that a recall is necessary, the Administrator finds that voluntary recall by the registrant and others in the chain of distribution may be as safe and effective as a mandatory recall, the Administrator shall request the registrant of the pesticide to submit, within 60 days of the request, a plan for the voluntary recall of the pesticide. If such a plan is requested and submitted, the Administrator shall approve the plan and order the registrant to conduct the recall in accordance with the plan unless the Administrator determines, after an informal hearing, that the plan is inadequate to protect health or the environment.

(3) MANDATORY RECALL.—If, after determining under paragraph (1) that a recall is necessary, the Administrator does not request the submission of a plan under paragraph (2) or finds such a plan to be inadequate, the Administrator shall issue a regulation that prescribes a plan for the recall of the pesticide. A regulation issued under this paragraph may apply to any person who is or was a registrant, distributor, or seller of the pesticide, or any successor in interest to such a person.

(4) RECALL PROCEDURE.—A regulation issued under this subsection may require any person that is subject to the regulation to—

(A) arrange to make available one or more storage facilities to receive and store the pesticide to which the recall program applies, and inform the Administrator of the location of each such facility;

(B) accept and store at such a facility those existing stocks of such pesticide that are tendered by any other person who obtained the pesticide directly or indirectly from the person that is subject to such regulation;

(C) on the request of a person making such a tender, provide for proper transportation of the pesticide to a storage facility; and

(D) take such reasonable steps as the regulation may prescribe to inform persons who may be holders of the pesticide of the terms of the recall regulation and how those persons may tender the pesticide and arrange for transportation of the pesticide to a storage facility.

(5) CONTENTS OF RECALL PLAN.—A recall plan established under this subsection shall include—

(A) the level in the distribution chain to which the recall is to extend, and a schedule for recall; and

(B) the means to be used to verify the effectiveness of the recall.

(6) REQUIREMENTS OR PROCEDURES.—No requirement or procedure imposed in accordance with paragraph (2) or (3) of subsection (a) may require the recall of existing stocks of the pesticide except as provided by this subsection.

(c) STORAGE COSTS.—

(1) SUBMISSION OF PLAN.—A registrant who wishes to become eligible for reimbursement of storage costs incurred as a result of a recall prescribed under subsection (b) for a pesticide whose registration has been suspended and canceled shall, as soon as practicable after the suspension of the registration of the pesticide, submit to the Administrator a plan for the storage and disposal of the pesticide that meets criteria established by the Administrator by regulation.

(2) REIMBURSEMENT.—Within a reasonable period of time after such storage costs are incurred and paid by the registrant, the Administrator shall reimburse the registrant, on request, for—

(A) none of the costs incurred by the registrant before the date of submission of the plan referred to in paragraph (1) to the Administrator;

(B) 100 percent of the costs incurred by the registrant after the date of submission of the plan to the Administrator or the date of cancellation of the registration of the pesticide, whichever is later, but before the approval of the plan by the Administrator;

(C) 50 percent of the costs incurred by the registrant during the 1-year period beginning on the date of the approval of the plan by the Administrator or the date of cancellation of the registration of the pesticide, whichever is later;

(D) none of the costs incurred by the registrant during the 3-year period beginning on the 366th day following approval of the plan by the Administrator or the date of cancellation of the registration of the pesticide, whichever is later; and

(E) 25 percent of the costs incurred by the registrant during the period beginning on the first day of the 5th year following the date of the approval of the plan by the Administrator or the date of cancellation of the registration of the pesticide, whichever is later, and ending on the date

that a disposal permit for the pesticide is issued by a State or an alternative plan for disposal of the pesticide in accordance with applicable law has been developed.

(d) ADMINISTRATION OF STORAGE, DISPOSAL, TRANSPORTATION, AND RECALL PROGRAMS.—

(1) VOLUNTARY AGREEMENTS.—Nothing in this section shall be construed as preventing or making unlawful any agreement between a seller and a buyer of any pesticide or other substance regarding the ultimate allocation of the costs of storage, transportation, or disposal of a pesticide.

(2) RULE AND REGULATION REVIEW.—Section 25(a)(4) shall not apply to any regulation issued under subsection (a)(2) or (b).

(3) LIMITATIONS.—No registrant shall be responsible under this section for a pesticide the registration of which is held by another person. No distributor or seller shall be responsible under this section for a pesticide that the distributor or seller did not hold or sell.

(4) SEIZURE AND PENALTIES.—If the Administrator finds that a person who is subject to a regulation or order under subsection (a)(2) or (b) has failed subsstantially to comply with that regulation or order, the Administrator may take action under section 13 or 14 or obtain injunctive relief under section 16(c) against such person or any successor in interest of any such person.

(e) CONTAINER DESIGN.—

(1) PROCEDURES.—

(A) Not later than 3 years after the effective date of this subsection, the Administrator shall, in consultation with the heads of other interested Federal agencies, promulgate regulations for the design of pesticide containers that will promote the safe storage and disposal of pesticides.

(B) The regulations shall assure, to the fullest extent practicable, that the containers—

(i) accommodate procedures used for the removal of pesticides from the containers and the rinsing of the containers;

(ii) facilitate the safe use of the containers, including elimination of splash and leakage of pesticides from the containers;

(iii) facilitate the safe disposal of the containers; and

(iv) facilitate the safe refill and reuse of the containers.

(2) COMPLIANCE.—The Administrator shall require compliance with the regulations referred to in paragraph (1) not later than 5 years after the effective date of this subsection.

(f) PESTICIDE RESIDUE REMOVAL.—

(1) PROCEDURES.—

(A) Not later than 3 years after the effective date of this subsection, the Administrator shall, in consultation with the heads of other interested Federal agencies, promulgate regulations prescribing procedures and standards for the removal of pesticides from containers prior to disposal.

(B) The regulations may—

(i) specify, for each major type of pesticide container, procedures and standards providing for, at a minimum, triple rinsing or the equivalent degree of pesticide removal;

(ii) specify procedures that can be implemented promptly and easily in various circumstances and conditions;

(iii) provide for reuse, whenever practicable, or disposal of rinse water and residue; and

(iv) be coordinated with requirements for the rinsing of containers imposed under the Resource Conservation and Recovery Act of 1976 (42 U.S.C. 6901 et seq.).

(C) Nothing in this subsection shall affect the authorities or requirements concerning pesticide containers under the Resource Conservation and Recovery Act of 1976.

(D) The Administrator may, at the discretion of the Administrator, exempt products intended solely for household use from the requirements of this subsection.

(2) COMPLIANCE.—Effective beginning 5 years after the effective date of this subsection, a State may not exercise primary enforcement responsibility under section 26, or certify an applicator under section II, unless the Administrator determines that the State is carrying out an adequate program to assure compliance with this subsection.

(g) PESTICIDE CONTAINER STUDY.—

(1) STUDY.—

(A) The Administrator shall conduct a study of options to encourage or require—

(i) the return, refill, and reuse of pesticide containers;

(ii) the development and use of pesticide formulations that facilitate the removal of pesticide residues from containers; and

(iii) the use of bulk storage facilities to reduce the number of pesticide containers requiring disposal.

(B) In conducting the study, the Administrator shall—

(i) consult with the heads of other interested Federal agencies, State agencies, industry groups, and environmental organizations; and

(ii) assess the feasibility, costs, and environmental benefits of encouraging or requiring various measures or actions.

(2) REPORT.—Not later than 2 years after the effective date of this subsection, the Administrator shall submit to Congress a report describing the results of the study required under paragraph (1).

SEC. 20 RESEARCH AND MONITORING.

(a) RESEARCH.—The * * *

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SEC. 21. SOLICITATION OF COMMENTS; NOTICE OF PUBLIC HEARINGS.

(a) *SECRETARY OF AGRICULTURE.*—The Administrator, before publishing regulations under this Act, shall solicit the views of the Sec-

retary of Agriculture in accordance with the procedure described in section 25(a).

(b) *VIEWS.*—In addition to any other authority relating to public hearings and solicitation of views, in connection with the suspension or cancellation of a pesticide registration or any other actions authorized under this Act, the Administrator may, at his discretion, solicit the views of all interested persons, either orally or in writing, and seek such advice from scientists, farmers, farm organizations, and other qualified persons as he deems proper.

(c) *NOTICE.*—In connection with all public hearings under this Act the Administrator shall publish timely notice of such hearings in the Federal Register.

SEC. 22 DELEGATION AND COOPERATION.

(a) DELEGATION.—* * *

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(c) OCCUPATIONAL SAFETY OR HEALTH AUTHORITY.—

(1) IN GENERAL.—In exercising any authority under this Act, the Administrator shall not, for the purposes of section 4(b)(I) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653(b)(1)), be considered to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health to the extent that the Administrator and the Secretary of Labor by agreement specify that such exercise of authority by the Administrator under this Act is not to be considered an exercise of statutory authority for purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970.

(2) COORDINATION.—To ensure the safety and health of workers, the Administrator and the Secretary of Labor shall seek to reach such agreements and to coordinate the exercise of their statutory authority.

(d) USE OF DETERMINATIONS, FINDINGS, OR GUIDELINES MADE UNDER OTHER LAWS.—Before the Administrator uses, under this Act, a determination, finding, or guideline that is made under another Federal or State law, the Administrator shall consult with Federal or State authorities that issued the determination, finding, or guideline and shall assure that the actions of the Administrator—

(1) are based on the best scientific and commercial data available; and

(2) have been formulated under procedures that afforded an opportunity for comment by affected parties.

SEC. 23. STATE COOPERATION, AID, AND TRAINING.

[(a) COOPERATIVE AGREEMENTS.—The Administrator may enter into cooperative agreements with States and Indian tribes—

[(1) to delegate to any State or Indian tribe the authority to cooperate in the enforcement of this Act through the use of its personnel or facilities, to train personnel of the State or Indian tribe to cooperate in the enforcement of this Act, and to assist States and Indian tribes in implementing cooperative enforcement programs through grant-in-aid; and

[(2) to assist States in developing and administering State programs, and Indian tribes that enter into cooperative agree-

ments, to train and certify applicators consistent with the standards the Administrator prescribes.

Effective with the fiscal year beginning October 1, 1978, there are authorized to be appropriated annually such funds as may be necessary for the Administrator to provide through cooperative agreements an amount equal to 50 percent of the anticipated cost to each State or Indian tribe, as agreed to under such cooperative agreements, of conducting training and certification programs during such fiscal year. If funds sufficient to pay 50 percent of the costs for any year are not appropriated, the share of each State and Indian tribe shall be reduced in a like proportion in allocating available funds.]

(a) COOPERATIVE AGREEMENTS.

(1) PURPOSES.—The Administrator may enter into cooperative agreements with States and Indian tribes for the following:

(A) To delegate to any State or Indian tribe the authority to cooperate in the enforcement of this Act through the use of its personnel or facilities, to train personnel of the State or Indian tribe to cooperate in the enforcement of this Act, and to assist States and Indian tribes in implementing cooperative enforcement programs through grants.

(B) To provide an amount equal to 50 percent of the anticipated cost of each State or Indian tribe, as prescribed under such cooperative agreements, of conducting training programs for certification of applicators. Funds shall be distributed among States and Indian tribes on a formula basis, as developed cooperatively between the Secretary of Agriculture and the Administrator.

(C) To provide an amount equal to 50 percent of the anticipated cost to each State or Indian tribe, as prescribed under such cooperative agreements, of conducting pesticide certification and licensing programs, and in the case of a State, for administering the State plan of each State approved under [section 4] section 11(a)(2). Funds shall be distributed among the States and Indian tribes on a formula basis as specified by the Administrator.

(2) AUTHORIZATION FOR APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for cooperative agreements and grants under this subsection.

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SEC. 24. AUTHORITY OF STATES.

[(a) A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act.]

(a) STATE REGULATION.—

(1) IN GENERAL.—A State may regulate the sale or use of any Federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act.

(2) HOUSEHOLD ANTIMICROBIAL PESTICIDES.—

(A) This paragraph shall apply to any household antimicrobial pesticide if—

(i) the pesticide is a formulated end-use product that, as registered, is not intended for use on food or feed;

(ii) the pesticide has been registered under section 3(c)(5), or reregistered under section [*3A*] *4, after the effective date of this subsection;*

(iii) the Administrator has determined that the product as so registered or reregistered poses no significant toxicological concern when used in accordance with the labeling;

(iv) the Administrator has published the determination of no significant toxicological concern in the Federal Register;

(v) the registrant of the product has offered, at the time the registrant provides the final product label to the Administrator, to provide under the conditions of this Act to the appropriate State authority any data submitted by the registrant to the Administrator in support of the registration; and

(vi) at least 45 days have elapsed from the date on which an application for State registration has been filed.

(B) A State may not prohibit any sale or use permitted under this Act of a pesticide described in subparagraph (A) for which an application for State registration has been filed unless and until the State has finally acted on such application pursuant to applicable State law.

(C) This paragraph shall cease to be effective 5 years after the date of the enactment of this subsection and shall not be construed during the 5 year effective period to—

(i) preclude a State from requiring in the State registration process submission of additional data beyond that required by the Administrator; or

(ii) otherwise affect State authority to regulate the sale or use of a pesticide when final action is taken under State law.

(b) *UNIFORMITY.*—Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this Act.

[(c)(1) A] *(c) ADDITIONAL USES.—*

(1) A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this Act and if registration for such use has not previously been denied, disapproved, or canceled by the Administrator. Such registration shall be deemed registration under section 3 for all purposes of this Act, but shall authorize distribution and use only within such State. *Such registration shall expire and be of no further effect, without further action by the Administator—*

(A) at the end of the period, if any, provided as the duration of the registration by the State that approved it; or

(B) 10 days after the date the Administrator publishes in the Federal Register a notice stating that the State that issued the registration has informed the Administrator

that the State no longer desires the registration to continue in effect.

(2) A registration issued by a State under this subsection shall not be effective for more than ninety days if disapproved by the Administrator within that period. Prior to disapproval, the Administrator shall, except as provided in paragraph (3) of this subsection, advise the State of the Administrator's intention to disapprove and the reasons therefor, and provide the State time to respond. The Administrator shall not prohibit or disapprove a registration issued by a State under this subsection (A) on the basis of lack of essentiality of a pesticide or (B) except as provided in paragraph (3) of this subsection, if its composition and use patterns are similar to those of a federally registered pesticide. *The Administrator shall establish criteria that define the conditions under which a special local needs registration may be disapproved, taking into account geographic patterns of use.*

* * * * * * *

(d) DIFFERENCES IN USAGE AND RISK.—In promulgating any regulations or policies pertaining to the sale or use of pesticides within a State, the State may take into account the difference in concept and usage between various classes of pesticides and the differences in environmental risk and the appropriate data for evaluating such risk between agricultural and nonagricultural pesticides.

SEC. 25. AUTHORITY OF ADMINISTRATOR.

[(a)(1) REGULATIONS.—The] *(a) IN GENERAL.—(1) REGULATIONS.*—The Administrator is authorized in accordance with the procedure described in paragraph (2), to prescribe regulations to carry out the provisions of this Act. Such regulations shall take into account the difference in concept and usage between various class of pesticides and differences in environmental risk and the appropriate data for evaluating such risk between agricultural and nonagricultural pesticides.

[(2) PROCEDURE.—]

(2) Procedure.—

(A) [PROPOSED REGULATIONS.—]At least 60 days prior to signing any proposed regulation for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation. If the Secretary comments in writing to the Administrator regarding any such regulation within 30 days after receiving it, the Administrator shall publish in the Federal Register (with the proposed regulation) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 30 days after receiving it, the Administrator may sign such regulation of publication in the Federal Register any time after such 30-day period notwithstanding the foregoing 60-day time requirement.

(B) [FINAL REGULATIONS.—]At least 30 days prior to signing any regulation in final form publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation. If the Secretary comments

in writing to the Administrator regarding any such final regulation within 15 days after receiving it, the Administrator shall publish in the Federal Register (with the final regulation) the comments of the Secretary, if requested by the Secretary, and the response of the Administrator concerning the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 15 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register at any time after such 15-day period notwithstanding the foregoing 30-day time requirement. In taking any final action under this subsection, the Administrator shall include among those factors to be taken into account the effect of the regulation on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such effect.

(C) [TIME REQUIREMENTS.—] The time requirements imposed by subparagraphs (A) and (B) may be waived or modified to the extent agreed upon by the Administrator and the Secretary.

(D) [PUBLICATION IN THE FEDERAL REGISTER.—] The Administrator shall, simultaneously with any notification to the Secretary of Agriculture under this paragraph prior to the issuance of any proposed or final regulation, publish such notification in the Federal Register.

(3) CONGRESSIONAL COMMITTEES.—At such time as the Administrator is required under paragraph (2) of this subsection to provide the Secretary of Agriculture with a copy of proposed regulations and a copy of the final form of regulations, he shall also furnish a copy of such regulations to the Committee on Agriculture of the House of Representatives and the [Committee on Agriculture and Forestry] *Committee on Agriculture, Nutrition, and Forestry* of the Senate.

[(4) If the Administrator finds, in accordance with standards set forth in regulations issued under section 25 of this Act, that a State is not capable of exercising adequate controls to assure that State registration under this section will be in accord with the purposes of this Act or has failed to exercise adequate controls, the Administrator may suspend the authority of the State to register pesticides until such time as the Administrator is satisfied that the State can and will exercise adequate controls. Prior to any such suspension, the Administrator shall advise the State of the Administrator's intention to suspend and the reasons therefor and provide the States time to respond.]

(4) CONGRESSIONAL REVIEW OF REGULATIONS.—Simultaneously with the promulgation of any rule or regulation under this Act, the Administrator shall transmit a copy thereof to the Secretary of the Senate and the Clerk of the House of Representatives. The rule or regulation shall not become effective until the passage of 60 calendar days after the rule or regulation is so transmitted.

* * * * * * *

(c) OTHER AUTHORITY.—The Administrator, after notice and opportunity for hearing *or by regulation* is authorized—

* * * * * * *

(5) to [prescribe regulations requiring] *require* any pesticide to be colored or discolored if he determines that such requirement is feasible and is necessary for the protection of health and the environment; and

* * * * * * *

(d) SCIENTIFIC ADVISORY PANEL.—[The] *Except with respect to a referral under section 3(c)(8)(F), the* Administrator shall submit to an advisory panel for comment as to the impact on health and the environment of the action proposed in notices of intent issued under section 6(b) and of the proposed and final form of regulations issued under section 25(a) within the same time periods as provided for the comments of the Secretary of Agriculture under such sections. The time requirements for notices of intent and proposed and final forms of regulation may not be modified or waived unless in addition to meeting the requirements of section 6(b) or 25(a), as applicable, the advisory panel has failed to comment on the proposed action within the prescribed time period or has agreed to the modification or waiver. The Administrator shall also solicit from the advisory panel comments, evaluations, and recommendations for operating guidelines to improve the effectiveness and quality of scientific analyses made by personnel of the Environmental Protection Agency that lead to decisions by the Administrator in carrying out the provisions of this Act. The comments, evaluations, and recommendations of the advisory panel submitted under this subsection and the response of the Administrator shall be published in the Federal Register in the same manner as provided for publication of the comments of the Secretary of Agriculture under such sections. The chairman of the advisory panel, after consultation with the Administrator, may create temporary subpanels on specific projects to assist the full advisory panel in expediting and preparing its evaluations, comments, and recommendations. The subpanels may be composed of scientists other than members of the advisory panel, as deemed necessary for the purpose of evaluating scientific studies relied upon by the Administrator with respect to proposed action. Such additional scientists shall be selected by the advisory panel. The panel referred to in this subsection shall [consist of 7 members] *be permanent and consist of 9 members* appointed by the Administrator from a list of 12 nominees, 6 nominated by the National Institutes of Health and 6 by the National Science Foundation, utilizing a system of staggered terms of appointment. Members of the panel shall be selected on the basis of their professional qualifications to assess the effects of the impact of pesticides on health and the environment. To the extent feasible to insure multidisciplinary representation, the panel membership shall include representation from the disciplines of toxicology, pathology, environmental biology, and related sciences. If a vacancy occurs on the panel due to expiration of a term, resignation, or any other reason, each replacement shall be selected by the Administrator from a group of 4 nominees, 2 submitted by each of the nominating enti-

ties named in this subsection. The Administrator may extend the term of a panel member until the new member is appointed to fill the vacancy. If a vacancy occurs due to resignation, or reason other than expiration of a term, the Administrator shall appoint a member to serve during the unexpired term utilizing the nomination process set forth in this subsection. Should the list of nominees provided under this subsection be unsatisfactory, the Administrator may request an additional set of nominees from the nominating entities. The Administrator may require such information from the nominees to the advisory panel as he deems necessary, and he shall publish in the Federal Register the name, address, and professional affiliations of each nominee. Each member of the panel shall receive per diem compensation at a rate not in excess of that fixed for GS–18 of the General Schedule as may be determined by the Administrator, except that any such member who holds another office or position under the Federal Government the compensation for which exceeds such rate may elect to receive compensation at the rate provided for such other office or position in lieu of the compensation provided by this subsection. In order to assure the objectivity of the advisory panel, the Administrator shall promulgate regulations regarding conflicts of interest with respect to the members of the panel. [The advisory panel established under this subsection shall terminate September 30, 1987.] In performing the functions assigned by this Act, the panel shall consult and coordinate its activities with the Science Advisory Board established under the Environmental Research, Development, and Demonstration Authorization Act of 1978. Whenever the Administrator exercises authority under section 6(c) of this Act to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly submit to the advisory panel for comment, as to the impact on health and the environment, the action taken to suspend the registration of such pesticide.

(e) PEER REVIEW.—The Administrator shall, by written procedures, provide for peer review with respect to the design, protocols, and conduct of major scientific studies conducted under this Act by the Environmental Protection Agency or by any other Federal agency, any State or political subdivision thereof, or any institution or individual under grant, contract, or cooperative agreement from or with the Environmental Protection Agency. In such procedures, the Administrator shall also provide for peer review, using the advisory panel established under subsection (d) of this section or appropriate experts appointed by the Administrator from a current list of nominees maintained by such panel, with respect to the results of any such scientific studies relied upon by the Administrator with respect to actions the Administrator may take relating to the change in classification, suspension, or cancellation of a pesticide[: *Provided,* That whenever]. *Whenever* the Administrator determines that circumstances do not permit the peer review of the results of any such scientific study prior to the Administrator's exercising authority under section 6(c) of this Act to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly thereafter provide for the conduct of peer review as provided in this sentence. The eval-

uations and relevant documentation constituting the peer review that relate to the proposed scientific studies and the results of the completed scientific studies shall be included in the submission for comment forwarded by the Administrator to the advisory panel as provided in subsection (d). As used in this subsection, the term "peer review" shall mean an independent evaluation by scientific experts, either within or outside the Environmental Protection Agency, in the appropriate disciplines.

(f) WORKER HEALTH AND SAFETY.—

(1) IN GENERAL.—

(A) The Administrator, as soon as practicable after the effective date of this subsection, shall promulgate regulations that require the protection, as appropriate and necessary, of employees who mix, load, or apply pesticides and agricultural employees who work in pesticide-treated areas.

(B) The Administrator shall promulgate regulations that provide for the training, as appropriate and necessary, of employees who mix, load, or apply pesticides. Any training requirement that may be established by the Administrator under this subparagraph shall not apply to any person who is required to receive the training described in subsection (d) or (e) of section 4.

(C) For purposes of subparagraphs (A) and (B), the term "employees" shall not include employees occupationally exposed to pesticides or pesticide residues as a result of the use of pesticides on livestock or other animals.

(2) RULEMAKING PROCEDURES.—

(A) The Administrator shall promulgate regulations under paragraph (1) for employees not described in subparagraph (B) not later than 3 years after the effective date of this subsection.

(B) The Administrator shall provide a period of at least 6 months for comments on proposed regulations issued under paragraph (I) that apply to agricultural employees who mix, load, or apply pesticides or who work in pesticide-treated areas. Such regulations shall be promulgated not later than 2 years after the effective date of this subsection.

(3) REPORT ON REGULATIONS.—Not later than 6 months after the date of the publication of the notice of proposed rulemaking issued for the regulations for employees described in paragraph (2)(B) to be promulgated under paragraph (1), the Secretary of Agriculture shall submit to the Administrator a report on the impact, cost, and effectiveness of such regulations on the agricultural community. The Secretary shall submit a copy of such report to Congress.

(4) COPY OF REGULATIONS.—Simultaneously with the promulgation of regulations under paragraph (I), the Administrator shall transmit a copy of such regulations to the Secretary of the Senate and the Clerk of the House of Representatives. Such regulations may not become effective until the expiration of 120 days after the date such regulations are so transmitted.

SEC. 26. STATE PRIMARY ENFORCEMENT RESPONSIBILITY.

(a) *IN GENERAL.*—For the purposes of this Act, a State shall have primary enforcement responsibility for pesticide use violations during any period for which the Administrator determines that such State—

(1) has adopted adequate pesticide use laws and regulations[; *Provided,* That the], *except that the* Administrator may not require a State to have pesticide use laws that are more stringent than this Act;

(2) has adopted and is implementing adequate procedures for the enforcement of such State laws and regulations; and

(3) will keep such records and make such reports showing compliance with paragraphs (1) and (2) of this subsection as the Administrator may require by regulation.

(b) *SPECIAL RULES.*—Notwithstanding the provisions of subsection (a) of this section, any State that enters into a cooperative agreement with the Administrator under section 23 of this Act for the enforcement of pesticide use restrictions shall have the primary enforcement responsibility for pesticide use violations. Any State that has a plan approved by the Administrator in accordance with the requirements of [section 4] *section 11* of this Act that the Administrator determines meets the criteria set out in subsection (a) of this section shall have the primary enforcement responsibility for pesticide use violations. The Administrator shall make such determinations with respect to State plans under section 4 of this Act in effect on the date of enactment of the Federal Pesticide Act of 1978 not later than six months after that date.

(c) *ADMINISTRATOR.*—The Administrator shall have primary enforcement responsibility for those States that do not have primary enforcement responsibility under this Act. [Not withstanding the provisions of section 2(e)(1) of this Act] *Notwithstanding section 2(rr),* during any period when the Administrator has such enforcement responsibility, section [8(b) of this Act] *9* shall apply to the books and records of commercial applicators and to any applicator who holds or applies pesticides, or use dilutions of pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and section [9(a) of this Act] *9* shall apply to the establishment or other place where pesticides or devices are held for application by such persons with respect to pesticides or devices held for such application.

(d) EXPIRATION.—Notwithstanding subsections (a) and (b), the primary enforcement responsibility of a State under this section for pesticide use violations shall expire on September 1, 1991, unless the Administrator determines that the State has the authority to impose civil and criminal penalties at least as stringent as those provided in section 14.

SEC. 27. FAILURE BY THE STATE TO ASSURE ENFORCEMENT OF STATE PESTICIDE USE REGULATIONS.

(a) *REFERRAL.*—Upon receipt of any complaint or other information alleging or indicating a significant violation of the pesticide use provisions of this Act, the Administrator shall refer the matter to the appropriate State officials for their investigation of the matter consistent with the requirements of this Act. [If, within

thirty days, the State has not commenced appropriate enforcement action, the Administrator may act upon the complaint or information to the extent authorized under this Act.] *If a State—*

(1) does not promptly initiate appropriate investigative action after receiving such referral; or

(2) does not initiate appropriate enforcement action within 90 days after receipt of such referral,

the Administrator may act on such complaint or information in accordance with this Act.

(b) *NOTICE.*—Whenever the Administrator determines that a State having primary enforcement responsibility for pesticide use violations is not carrying out (or cannot carry out due to the lack of adequate legal authority) such repsonsibility, the Administrator shall notify the State. Such notice shall specify those aspects of the administration of the State program that are determined to be inadequate. The State shall have ninety days after receipt of the notice to correct any deficiencies. If after that time the Administrator determines that the State program remains inadequate, the Administrator may rescind, in whole or in part, the State's primary enforcement responsibility for pesticide use violations.

(c) *CONSTRUCTION.*—Neither section 26 of this Act nor this section shall limit the authority of the Administrator to enforce this Act, where the Administrator determines that emergency conditions exist that require immediate action on the part of the Administrator and the State authority is unwilling or unable adequately to respond to the emergency.

SEC. 28. IDENTIFICATION OF PESTS; COOPERATION WITH DEPARTMENT OF AGRICULTURE'S PROGRAM.

The Administrator, * * *

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SEC. 29 ANNUAL REPORT.

The Administrator * * *

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SEC. 30. SEVERABILITY.

If any * * *

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SEC. 31. PESTICIDES IN GROUND WATER.

(a) LEACHING POTENTIAL.—

(1) CRITERIA.—The Administrator shall publish and seek comment on criteria to determine whether a pesticide has the potential to leach into ground water. Such criteria may include factors such as—

(A) the intended use of the pesticide;

(B) the timing, rate, and method of application for the pesticide;

(C) the mobility of the pesticide in soil and water under various conditions; and

(D) the rates of degradation of the pesticide in soil and water under various conditions.

(2) INFORMATION.—Each person seeking to register or reregister a pesticide under this Act shall submit such data and information as the Administrator shall require with respect to the potential for the pesticide to leach into ground water and the destination and method of transportation of the pesticide.

(3) DETERMINATION OF POTENTIAL TO LEACH.—At the time of registering or reregistering a pesticide (and using the criteria developed under paragraph (1)) the Administrator shall determine whether the pesticide has the potential to leach into ground water.

(4) DETERMINATION OF NECESSITY FOR MONITORING DATA.—If the Administrator determines that a pesticide has the potential to leach into ground water as described in this subsection or the pesticide has been detected at ground water sampling points in three or more locations, the Administrator shall also determine whether monitoring data on the presence of the pesticide in ground water are required to register or maintain in effect an existing registration of the pesticide.

(b) NOTIFICATION.—

(1) REQUIREMENT.—When a registrant of a pesticide obtains or learns of reliable analytical data that a pesticide has—

(A) been detected at any ground water sampling point and no ground water residue guidance level has been issued for the pesticide under section 1429 of the Public Health Service Act;

(B) has been detected at a ground water sampling point at a concentration higher than known previously to have been reported to the Administrator at such ground water sampling point; or

(C) has been detected at any ground water sampling point at a concentration at or greater than 20 percent of the ground water residue guidance level issued for the pesticide under section 1429 of the Public Health Service Act;

the registrant shall file a report containing such information within 15 working days with the Administrator, the State in which the ground water sampling point is located, and the owner of the property in which the ground water sampling point is located; if known.

(2) CONTENT OF REPORT.—A report required by paragraph (1) for detection of a pesticide shall contain information known to the registrant of the pesticide on the level of detection of the pesticide, the frequency of detection of the pesticide, location (including depth) where the pesticide was detected, date of the pesticide detection, well construction if the pesticide was detected in a well, soil type where the pesticide was detected, and analytical method used to make the pesticide detection, including information on the precision, accuracy, and limits of the method of detection and any quality assurance and control procedures used in the pesticide detection.

(c) REVIEW FOR FURTHER ACTION.—On receiving information of a detection of a pesticide at any ground water sampling point, the Administrator shall promptly review the information to determine the reliability of the detection and to determine whether further action should be taken to protect ground water.

(d) MONITORING—

(1) CONFIRMATION OF DETECTIONS.—If the Administrator receives reliable, analytical data indicating that—

(A) a pesticide has been detected in a drinking water well;

(B) the concentration of the pesticide equals or exceeds any ground water residue guidance level issued under subsection (d) for that pesticide, and

(C) the presence of the pesticide in the drinking water well may be the result of use of the pesticide in accordance with the labeling on the pesticide or widespread and commonly recognized practices involving the pesticide.

the Administrator may require the registrant of the pesticide detected to conduct such analysis of samples of ground water from the drinking water well involved as is necessary to determine whether the pesticide is present at a concentration that equals or exceeds such ground water residue guidance level. A monitoring requirement imposed under this paragraph shall be completed within 90 days of notice to the registrant. The procedures set forth in section 3(c)(2)(B) shall govern any monitoring requirement imposed under this paragraph.

(2) REQUIREMENT FOR MONITORING.—If the Administrator determines that additional data on the presence of a pesticide in ground water are required to maintain in effect an existing registration of the pesticide, the Administrator may, under section 3(c)(2)(B), require the registrant of the pesticide to conduct ground water monitoring. The Administrator shall consult with the Secretary of Agriculture, the heads of other appropriate Federal agencies, and the States concerning the design and scope of monitoring requirements imposed under this paragraph. The design and the scope of the monitoring requirement should take into account all relevant information, including the magnitude and frequency of the detection of the pesticide involved, pattern of pesticide use and soil types involved in the detection, physical and chemical properties of the pesticide, rainfall patterns, well construction if the pesticide was detected in a well, rates of degradation, reliability and analytical accuracy of the detection, and results of State or other sponsored monitoring. To the extent feasible, monitoring should be at representative geographical and hydrogeological areas associated with locations and conditions of concern as determined by the Administrator.

(3) JUDICIAL REVIEW.—Monitoring requirements imposed under paragraph (2) shall be subject to judicial review under section 16.

(e) REGISTRATION AMENDMENTS.—

(1) REQUIREMENT.—

(A)(i) After reviewing reliable analytical data, the Administrator shall determine whether there is a reasonable likelihood that the ground water residue guidance level for a pesticide will be exceeded in drinking water wells in different localities. The Administrator shall provide for notice and opportunity for public comment on any determination under this clause and shall publish the determination in the Federal Register.

(ii) If the Administrator determines that there is a reasonable likelihood of exceeding such level in different localities, the Administrator shall promptly require amendments to the registration of the pesticide involved that are reasonably necessary to assure that the use of the pesticide in accordance with the amended registration will not cause the final ground water residue guidance level to be exceeded in drinking water wells.

(iii) The Administrator shall make such a determination public.

(iv) If the Administrator proposes to require registration amendments under this paragraph, the Administrator shall notify registrants of such amendments and shall publish notice of the determination in the Federal Register. Such notice shall include the determination of the Administrator whether the presence of the pesticide in drinking water wells appears to have been the result of use of the pesticide in accordance with the labeling or widespread and generally recognized practice.

(B)(i) After reviewing reliable analytical data, the Administrator shall determine whether there is a reasonable likelihood that the ground water residue guidance level for a pesticide will be exceeded in potential sources of drinking water in different localities.

(ii) If the Administrator determines that there is a reasonable likelihood that such level will be exceeded in different localities, the Administrator shall promptly require amendments to the registration of a pesticide involved that are reasonably necessary to ensure that use of the pesticide in accordance with the amended registration will not cause the final ground water residue guidance level to be exceeded in potential sources of drinking water.

(iii) If the Administrator proposes to require amendments under this paragraph, the Administrator shall notify registrants of such amendments.

(iv) In establishing such amendments, the Administrator shall—

(I) meet the requirements of subparagraph (A);

(II) take into account information submitted by States on land and ground water use classification or other governmental actions that coud affect when ground water may be used for drinking water; and

(III) consider the views of the Secretary of Agriculture, other heads of appropriate Federal agencies, and States as required in paragraph (2).

(2) CONSULTATION.—

(A) In taking action under paragraph (1), the Administrator shall consult with the Secretary of Agriculture and the State where the pesticide involved has been detected in any ground water sampling point and each other State in which there is significant use of the pesticide.

(B) The Administrator shall notify such State of the determination of the Administrator that there is a reasonable likelihood that the ground water residue guidance level

will be exceeded and shall provide the State with all information relevant to this determination subject to section 10(h).

(C) A State shall promptly provide the Administrator with information relevant to taking action under this section and shall make recommendations regarding necessary registration amendments with respect to the State.

(3) REASONABLE LIKELIHOOD.—

(A) for purposes of paragraph (1), there shall be a presumption that there is a reasonable likelihood that a ground water residue guidance level for a pesticide will be exceeded in drinking water wells if the pesticide is detected above 30 percent of the ground water residue guidance level, unless considering the other factors described in subparagraph (B), the Administrator determines, after notice and opportunity for public comment, that there is not such a reasonable likelihood.

(B) The circumstances surrounding the presence of the pesticide in ground water, taking into account all relevant information, include the frequency and time of occurrence at the site of detection and elsewhere, use patterns, soil types, physical and chemical properties of the pesticide, rainfall patterns, well construction, analytical accuracy, and rates of degradation.

(4) SCOPE OF AMENDMENTS.—

(A) Amendments to the registration of a pesticide may include—

(i) limitations on the purposes for and location at which the pesticide may be used, considering factors such as environmentally sensitive areas and conditions;

(ii) limitations on the rate at which the pesticide is applied;

(iii) limitations on the time or frequency of pesticide use;

(iv) limitations on the method of pesticide application, storage, handling, or disposal;

(v) reporting or other requirements, including label changes or changes in classification;

(vi) requirements for the training or certification of pesticide applicators or other persons using the pesticide;

(vii) required site-specific responses; or

(viii) any other requirement under this Act to ensure that the ground water residue guidance level for such pesticide will not be exceeded.

(B) The amendments to the registration of a pesticide should, to the extent feasible, be directed to the same or similar uses of the pesticide, similar geographical and hydrogeological areas, and other similar conditions that led to the determination under subparagraph (A) or (B) of paragraph (1).

(C) In taking regulatory action under this subsection, the Administrator may utilize recommendations provided by the States under paragraph (2).

(D) In requiring such amendments, the Administrator shall consider the effect of any voluntary actions by registrants or other persons, including actions by the State to prevent the ground water residue guidance level from being exceeded, and compliance with other environmental laws.

(5) EFFECTIVENESS AMENDMENTS.—If the Administrator has imposed registration amendments on the use of a pesticide according to this subsection, the Administrator shall—

(A) periodically review reliable analytical data on the occurrence of the pesticide at ground water sampling points representative of the locations at which the pesticide is used to determine whether such amendments are effective in meeting the requirements of paragraph (1);

(B) require additional registration amendments, if such amendments are necessary to assure that the ground water residue guidance level for such pesticide will not be exceeded in drinking water wells and potential sources of drinking water; and

(C) report to the Congress not later than January 31, 1990, and every 2 years thereafter, on whether any such initial or additional amendments have been effective in meeting the requirements of paragraph (1), and make the report available to affected States on request.

(6) PROCEDURES.—Registration amendments under paragraph (1) shall be imposed in accordance with the procedures required by this Act.

(f) RESPONSE TO GROUND WATER CONTAMINATION.—

(1) REQUIREMENT.—

(A) If the Administrator determines that a pesticide is present in a drinking water well in a concentration that exceeds the final ground water residue guidance level and that the presense of the pesticide in a drinking water well may be the result of use of the pesticide in accordance with the labeling on the pesticide or as a result of widespread and commonly recognized practice involving the pesticide, the Administrator shall—

(i) notify the State in which the drinking water well is located of the determination of the Administrator; and

(ii) provide the State, subject to section 10(h), with all information relevant to the determination.

(B) Such State shall take action within 90 days of such notification to prevent potential adverse effects on human health and the environment from such pesticide. In taking such action, the State shall take appropriate action regarding the sale or use of the pesticide detected at such drinking water well to bring and retain concentrations of the pesticide at such drinking water well at or below the final ground water residue guidance level applicable to the pesticide.

(2) ACTION BY THE ADMINISTRATOR.—

(A) If—

(i) a State does not have the authority to take action required by paragraph (1) with respect to a pesticide de-

tected in a drinking water well or fails to take such action within the time period prescribed by such paragraph;

(ii) a pesticide is present in a drinking water well in the State at a concentration that exceeds the final ground water residue guidance level; and

(iii) the presence of the pesticide may be the result of use in accordance with the labeling or of widespread and commonly recognized practice,

the Administrator shall take appropriate action under this Act to bring and retain the concentration detected at such drinking water well at or below the final ground water residue guidance level applicable to the pesticide and may take such other action under this Act as the Administrator considers necessary to prevent potential adverse effects on human health and the environment from the pesticide at such drinking water well.

(B) The Administrator shall publish notice of the action in the Federal Register and take appropriate steps to inform all registrants, potentially affected persons, and interested members of the public. Such notice shall specify the factual findings and conclusions relied on in support of the decision.

(C) Any person adversely affected by an action or failure to act under this paragraph shall have an opportunity for an expedited hearing pursuant to the procedures set forth in section 6(c)(2), to determine whether the action was taken in accordance with this paragraph or whether the Administrator was required to take action.

(D) Notwithstanding any other provision of this Act, a hearing shall be held and a determination made under this subsection within 75 days after receipt of the request for such a hearing.

(E) The Administrator shall provide reasonable pesticide ingredient characteristics, predictive modeling, exposure and other relevant subjects. In addition, the Administrator shall provide information, to the extent reasonably available, on the alternative methods of pest control and on agricultural or other management practices that could minimize the presence of pesticides in ground water.

(i) SPECIAL REVIEW.—On receiving reliable analytical data that a pesticide has been detected above the ground water residue guidance level in ground water in a drinking water well or potential source of drinking water, the Administrator may initiate a public interim administrative review under section 3(c)(8) to determine whether the pesticide may cause unreasonable adverse effects on the environment from such use.

(j) SITE-SPECIFIC INFORMATION.—

(1) AVAILABILITY OF INFORMATION.—The Administrator shall enter into a memorandum of understanding with the Secretary of Agriculture, the Secretary of Commerce, and the Secretary of the Interior, for the purpose of developing information management systems and other techniques designed to make available information more useful to State and local officials and agri-

cultural producers, applicators, and other persons using the pesticide information on the soil, hydrology, climate, and other characteristics or specific sites of pesticide application to be used by such officials and users in developing practices and making application decisions that will prevent the contamination of ground water by pesticides.

ESTABLISHMENT OF COUNCIL.—

(A) Under the direction of the Administrator, a council shall be established to assist the Environmental Protection Agency in developing a site-specific pesticide information system.

(B) The council shall consist of experts on information management who have experience with information retrieval from the Environmental Protection Agency, the National Agricultural Library, the Soil Conservation Service, the United States Geological Survey, and the National Oceanographic and Atmospheric Administration.

(C) The council shall—

(i) review existing information retrieval and referral services that may be used to access information on soil, hydrology, climate, and other characteristics at specific sites important to pesticide application;

(ii) determine what information relevant to making site-specific pesticide decisions is available directly from existing data banks; and

(iii) based on these determinations develop and submit to the Administrator a plan for an information management system that would direct and assist users in gaining access to site-specific information available in printed and electronic form.

(3) CONSIDERATION BY ADMINISTRATOR.—The Administrator shall take the plans developed by the council into consideration when developing the site-specific pesticide information management system.

(4) AUTHORIZATION.—

(A) This subsection shall take effect to the extent that appropriations are made for it under subparagraph (B).

(B) To carry out this subsection, there are authorized to be appropriated $2,500,000 for each of the fiscal years 1988 through 1992.

(k) EFFECT ON OTHER PROVISIONS.—Nothing in this section shall limit the authority of the Administrator or of any State under other provisions of this Act or under any other law.

[SEC. 31. AUTHORIZATION OF APPROPRIATIONS.

[There is authorized to be appropriated to carry out this Act for the period beginning October 1, 1985, and ending September 30, 1986, $68,604,200 of which not more than $11,993,100 shall be available for research under this Act.]

SEC. 32. AUTHORIZATION FOR APPROPRIATIONS.

There is authorized to be appropriated to carry out this Act (other than section 23(a))—

(1) $103,363,500 for fiscal year 1988, of which not more than $13,735,500 shall be available for research under this Act;

(2) $112,414,200 for fiscal year 1989, of which not more than $14,343,600 shall be available for research under this Act;

(3) $116,673,400 for fiscal year 1990, of which not more than $14,978,200 shall be available for research under this Act;

(4) $123,305,800 for fiscal year 1991, of which not more than $15,625,900 shall be available for research under this Act; and

(5) $131,808,700 for fiscal year 1992, of which not more than $16,300,100 shall be available for research under this Act.

ACT OF AUGUST 4, 1965

AN ACT To facilitate the work of the Department of Agriculture, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

* * * * * * *

SEC. 2. (a) * * *

* * * * * * *

(c) The Secretary of Agriculture is authorized to make grants, for periods not to exceed five years in duration—

(1) to land-grant colleges and universities, research foundations established by land-grant colleges and universities, State agricultural experiment stations, and to all colleges and universities having a demonstrable capacity in food and agricultural research, as determined by the Secretary to carry out research to facilitate or expand promising breakthroughs in areas of the food and agricultural sciences of importance to the Nation; and

(2) to State agricultural experiement stations, land-grant colleges and universities, research foundations established by land-grant colleges and universities, colleges and universities receiving funds under the Act of October 10, 1962 (16 U.S.C. 582a et seq.) and accredited schools or colleges of veterinary medicine, to facilitate or expand ongoing State-Federal food and agricultural research programs that (A) promote excellence in research, (B) promote the development of regional research centers, (C) promote the research partnership between the Department of Agriculture and such colleges and universities, such research foundations or State agricultural experiment stations, or (D) facilitate coordination and cooperation of research among States.

The Secretary in making grants under paragraph (2)(B) shall provide support for the interregional project number 4 program (commonly referred to as the "IR4 program". No grant may be made under this subsection for any purpose for which a grant may be made under subsection (d) or for the planning, repairs, rehabilitation, acquisition, or construction of a building or facility. These grants shall be made without regard to matching funds. Four percent of the amount appropriated for any fiscal year to carry out

this subsection may be retained by the Secretary to pay administrative costs incurred by the Secretary to carry out this subsection.

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TITLE 21, UNITED STATES CODE

CHAPTER 9—FEDERAL FOOD, DRUG, AND COSMETIC ACT

§ 408. Tolerances for pesticide chemicals in or on raw agricultural commodities

(a) Any * * *

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(m) [The] *Except as provided in subsection (p), the* Secretary of Health, Education, and Welfare shall prescribe by regulations the procedure by which regulations under this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of regulations establishing tolerances, including the appointment of advisory committees and the procedure for referring petitions to such committees.

* * * * * * *

(p)(1)(A) If the registration of each pesticide containing a specific active or inert ingredient registered for use on a particular raw agricultural commodity—

(i) has been canceled by the Administrator under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.);

(ii) has voluntarily been canceled under such Act; or

(iii) has voluntarily been withdrawn under such Act;

due in whole or in part to dietary risks to humans, the Adminstrator, not later than 60 days after the effective date of such cancellation or after receipt of information of such withdrawal, shall revoke any tolerance established under subsection (b) for residues of such pesticide chemical in or on such commodity or any exemption from the need for such tolerance established under subsection (c). In revoking a tolerance or an exemption from a tolerance, the procedures required under section 553 of title 5, United States Code, shall be used.

(B) The effective date of a revocation under subparagraph (A) may be delayed to permit distribution in commerce of food that bears residues of the active or inert ingredient as the result of—

(i) the use of the canceled pesticide before the date of its cancellation;

(ii) the use of existing stocks of such pesticide as authorized under the order canceling the registration of the pesticide; or

(iii) unavoidable residual environmental contamination.

(2) If the registration of each pesticide containing a specific active or inert ingredient registered for use on a particular raw agricultural commodity has been suspended by the Administrator under the Federal Insecticide, Fungicide, and Rodenticide Act due in whole or in part to dietary risks to humans, the Administrator, not later

than 60 days after the effective date of such suspension, shall suspend any tolerance established under subsection (b) for residues of such pesticide chemical in or on such commodity or any exemption from the need for such tolerance established under subsection (c). The effective date of such suspension may be delayed to permit distribution in commerce of food that bears residues of the active or inert ingredient as the result of—

(A) the use of the suspended pesticide before the date of its suspension;

(B) the use of existing stocks of such pesticide as authorized under the order suspending the registration of the pesticide; or

(C) unavoidable residual environmental contamination

In suspending a tolerance or an exemption from a tolerance, the procedures required under section 553 of title 5, United States Code, shall be used. The suspension of a tolerance or an exemption from a tolerance for a pesticide chemical shall be effective as long as the registration of the pesticide to which the tolerance or exemption is applicable is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act. If the registration of the pesticide ceases to be suspended and is not canceled under such Act, the Administrator shall rescind any such suspension of a tolerance or exemption.

(3)(A) At the time the Administration makes a determination under section 4(h)(2) of the Federal Insecticide, Fungicide, the Rodenticide Act regarding an ingredient of a pesticide—

(i) any tolerance established under subsection (b) for residues of a pesticide chemical that is or contains such ingredient or any exemption from the need for such a tolerance established under subsection (c) or a food additive regulation for residues to a pesticide chemical established under section 409 shall be reassessed; and

(ii) the Administrator shall—

(I) make a determination whether such tolerance, exemption from tolerance, or regulation meets the requirements of this Act; and

(II) confirm, establish, amend, or revoke such tolerance, exemption, or regulation in accordance with the requirements of this section.

(B) Any tolerance, exemption, or regulation that is confirmed, established, or amended under subparagraph (A)(ii)(II) shall not become effective until the Administrator determines that a practical method for detecting residues in or on food or feed is available in order to enforce such tolerance, exemption, or regulation.

(4) Notwithstanding the foregoing provisions of this subsection, the Administrator, by regulation, may reasonably limit the application of a revocation or suspension of a tolerance or exemption from a tolerance as necessary to prevent the imposition of restrictions on the imports of a particular agricultural commodity from a particular country, except that no such limitation may be effected unless the Administrator determines—

(A) the tolerance or exemption satisfies the criteria of subsection (b) or (c); and

(B) there is not available an effective alternative pesticide that may legally be used on the particular agricultural commodity in such country.

TITLE 35, UNITED STATES CODE

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CHAPTER 14—ISSUE OF PATENT

Sec.
151. Issue of patent.

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158. Restoration of patent term for certain agricultural and chemical products

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§ 158. Restoration of patent term for certain agricultural and chemical products

(a) The term of a patent that claims a product subject to a regulatory review period, a method for using such a product, or a method for manufacturing such a product shall be extended, in accordance with this section, from the original expiration date of the patent if—

(1) the owner of record of the patent or its agent notifies the Commissioner in compliance with subsection (d),

(2) the product has been subject to regulatory review period before its commercial marketing or use,

(3) the term of the patent has never been extended under this section,

(4) the term of the patent has not expired before the Commissioner is notified under subsection (d), and

(5)(A) except as provided in subparagraph (B), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred, or

(B) in the case of a patent that claims a method of manufacturing the product that primarily uses recombinant DNA or hybridoma technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent.

(b) The rights derived from any patent the term of which is extended under this section shall during the period during which the patent is extended—

(1) in the case of any patent that claims a product, be limited to any use approved for the product before the expiratioin of the term of the patent under the provision of law under which the applicable regulatory review occurred,

(2) in the case of a patent that claims a method of using a product, be limited to any use claimed by the patent and ap-

proved for the product before the expiration of the term of the patent under the provision of law under which the applicable regulatory review occurred,

(3) in the case of a patent that claims a method of manufacturing a product, be limited to the method of manufacturing as used to make the product.

(c)(1) Subject to paragraph (2), the term of a patent shall be extended by the time equal to the regulatory review period that occurred after such patent was granted, except that—

(A) the term of any patent may not be extended for more than 5 years,

(B) no term of any extended patent may exceed 17 years from the date the product for which the patent was issued was first permitted to be commercially marketed or used,

(C) if the regulatory review period for a product began before the date of enactment of this section and if on such date the regulatory review period had not ended, the period of extension for the patent shall not exceed 2 years, and

(D) if the regulatory review period for a product began before the date of enactment of this section and if on such date the regulatory review period had been completed, there shall be no extension of the patent.

(2) In determining a regulatory review period for purposes of paragraph (1)—

(A) if an application or notice described in subparagraph (A)(ii), (B), or (C) of paragraph (4) of subsection (g) was rejected because of insufficiency of data or other required information, the period beginning on the date the application or notice was rejected for insufficiency of data and ending on the date the application or notice was subsequently accepted shall be excluded, except that if during such period the product sponsor conducts a major health or environmental effects test, the period during which such test is conducted shall not be excluded, and

(B) the regulatory review period shall be reduced by any period determined under subsection (e) during which the product sponsor did not act with due diligence.

(3) In no event shall more than one patent be extended for the same regulatory review period for any product.

(4) In the case of a pesticide, all formulations of such pesticide containing the identical active ingredient shall be considered the same pesticide and no pesticide may be the subject of more than one patent extension.

(d) To obtain an extension of the term of a patent under subsection (a), the owner of record of the patent or its agent shall notify the Commissioner, within 60 days after the termination of the regulatory review period for the product to which the patent relates, that the regulatory review period has ended. Such notification shall be in writing and shall—

(1) identify the Federal statute under which regulatory review occurred.

(2) state the dates on which the regulatory review period commenced and ended and identify the event that caused such period to begin.

(3) identify the product for which regulatory review was required,

(4) state that the requirements of the statute under which the regulatory review referred to in subsection (a)(2) occurred have been satisfied and commercial marketing or use of the product is not prohibited under the Federal statute identified under paragraph (1),

(5) identify the patent and any claim thereof to which the extension is applicable, identify any uses previously authorized, and state that the term of the patent has never been extended under this section and that no other patent has been extended for the regulatory review period for the product, and

(6) include such patent or other information as the Commissioner may require.

(e)(1) Within 60 days of the submittal of the extension notification under subsection (d), the Commissioner shall notify—

(A) the Secretary of Agriculture if the patent claims a plant or plant product or a method of using or manufacturing a plant or plant product, and

(B) the Administrator of the Environmental Protection Agency if the patent claims a pesticide subject to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), a chemical substance or mixture subject to the Toxic Substances Control Act (15 U.S.C. 2601 et seq.), or a method of using or manufacturing such a pesticide, substance, or mixture,

of the extension notification and shall submit to the Secretary or Administrator who is so notified a copy of the extension notification. Not later than 30 days after the receipt of the extension notification from the Commissioner, the Secretary or Administrator receiving the extension notice shall review the dates contained in such notification and determine the applicable regulatory review period, shall notify the Commissioner of the determination, and shall publish in the Federal Register a notice of such determination.

(2)(A) If a petition is submitted to the Secretary or Administrator making the determination under paragraph (1) not later than 180 days after the publication of a determination under paragraph (1) on which it may reasonably be determined that a product sponsor did not act with due diligence during an applicable regulatory review period, the Secretary or Administrator making the determination shall, in accordance with regulations promulgated by the Secretary or Administrator, determine if the product sponsor acted with the due diligence during the applicable regulatory review period. The Secretary or Administrator shall make such determination not later than 90 days after the receipt of a petition. The Administrator may not delegate the authority to make such determination to an office below the Assistant Administrator for Pesticides and Toxic Substances.

(B) The Secretary or Administrator making a determination under subparagraph (A) shall notify the Commissioner of the determination and shall publish in the Federal Register a notice of such determination, together with the factual and legal basis for such determination. Any interested person may request, within the 60-day period beginning on the publication of a determination, the Secretary or Adminstrator making the determination to hold a hearing

on the determination. Such a hearing shall be an informal hearing that is not subject to section 554, 556, or 557 of title 5, United States Code. If such a request is made within such period, the Secretary or Administrator shall hold such hearing not later than 30 days after the date of the request, or at the request of the person making the request, not later than 60 days after such date. The Secretary or Administrator who is holding the hearing shall provide notice of the hearing to the product sponsor and to any interested person and provide the product sponsor and any interested person an opportunity to participate in the hearing. Within 30 days after the completion of the hearing, such Secretary or Administrator shall affirm or revise the determination that was the subject of the hearing and notify the Commissioner of such affirmation or any revision of the determination and shall publish such affirmation or revision in the Federal Register.

(C) Failure of a product sponsor to act with due diligence during a regulatory review period shall not be a defense in any action involving the infringement of a patent.

(D) In a proceeding under this paragraph, the Secretary or Administrator may take into consideration the failure of a product sponsor to submit data that the product sponsor knew or reasonably should have known was necessary to support an application or notice described in paragraph (4) of subsection (g).

(E) For purposes of this paragraph, the term "due diligence" means that degree of attention, sustained directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.

(f)(1) The Commissioner shall determine whether a patent is eligible for extension under subsection (a) and whether the requirements of subsection (d) have been complied with. A determination that a patent is eligible for extension may be made by the Commissioner solely on the basis of the representations contained in the notification under subsection (d). If the Commissioner determines that the patent is eligible for extension and on receipt of a determination of the applicable regulatory review period under subsection (e), the Commissioner shall issue to the owner of record of the patent a certificate of extension, under seal, for the period prescribed by subsection (c). Such certificate shall be recorded in the official file of the patent and shall be considered as part of the original patent. The Commissioner shall publish in the Official Gazette of the Patent and Trademark Office a notice of such extension.

(2) If the term of a patent for which a notification has been submitted under subsection (d) would expire before a certificate of extension is issued or denied under paragraph (1), the Commissioner shall extend, until such determination is made, the term of the patent for periods of up to 1 year if the Commissioner determines that the patent is eligible for extension. Such periods of extension shall not exceed the regulatory review period calculated from the information provided in the notification submitted under subsection (d).

(g) As used in this section:

(1) the term "product" means—

(A) any pesticide subject to regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.);

(B) any chemical substance or mixture subject to regulation under the Toxic Substances Control Act (15 U.S.C. 2601 et seq.); and

(C) any plant or plant product that (i) is genetically altered, (ii) is defined as a plant pest or potential plant pest under the Federal Plant Pest Act (7 U.S.C. 150aa et seq.), and (iii) is subject to regulation under such Act.

(2) The term "major health or environmental effects test" means an experiment or study to determine or evaluate health or environmental effects that requires at least 6 months to conduct, not including any period for analysis or conclusions, and the data from which is submitted to receive permission for commercial marketing or use.

(3) The term "product sponsor" means any person who, with the consent of the patent owner, initiates testing or investigations, claims an exemption, or submits an application or notice described in paragraph (4).

(4) The term "regulatory review period" has the following meaning:

(A) With respect to a product that is a pesticide, the term means the sum of—

(i) the period beginning on the earlier of the date the product sponsor (I) initiates a major health or environmental effects test on such pesticide, or (II) requests, in accordance with regulations issued by the Administrator, the grant of an experimental use permit for the pesticide under section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136c), and ending on the date an application is submitted for registration of such pesticide pursuant to section 3 of such Act (7 U.S.C. 136a), and

(ii) the period beginning on the date an application is submitted, in accordance with regulations issued by the Administrator, for registration of such pesticide pursuant to section 3 of such Act and ending on the date such pesticide is first registered, either conditionally or fully, under such action.

(B) With respect to a product that is a chemical substance for which notice is required under section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) or that is a mixture that contains a substance for which such notice is required and—

(i) that is subject to a rule requiring testing under section 4(a) of such Act (15 U.S.C. 2603(a)), the term means a period commencing on the date the product sponsor has initiated the testing required in such rule and ending on the expiration of the notice period for such chemical substance or mixture under section 5 of such Act, or if an order or injunction is issued under section 5(e) or 5(f) of such Act, the date on which such order or injunction is dissolved or set aside, or

(ii) that is not subject to a testing rule under section 4 of such Act, the term means a period commencing on the earlier of the date the product sponsor—

(I) submits, in accordance with regulations issued by the Administrator, a notice under section 5 of such Act, or

(II) initiates a major health or environmental effects test on such chemical substance or mixture,

and ending on the expiration of the notice period for such substance under section 5 of such Act or if an order or injunction is issued under section 5(e) or 5(f) of such Act, the date on which such order or such injunction is dissolved or set aside.

(C) With respect to a product that is a plant or plant product, the term means the period beginning on the date an application is submitted under section 103 of the Federal Plant Pest Act (7 U.S.C. 150bb) for permission to move the plant or plant product in interstate commerce and ending on the date such application is approved.

(h) If information submitted by a product sponsor during a regulatory review period is considered a trade secret or confidential commercial or financial information under the law under which such regulatory review occurred, such information may only be disclosed under this section in accordance with such law. This subsection does not prohibit the Commissioner or the Administrator from identifying the patent owner, the product sponsor, the product, the patent, and any other information necessary to identify, describe, and calculate the regulatory review period in any notification, publication, or public record required by this section.

(i) The Commissioner, the Administrator, and the Secretary of Agriculture may establish such fees as appropriate to cover the costs of carrying out their respective duties and functions under this section.

(j)(1) Except as provided in paragraph (2), this section shall cease to be in effect on the expiration of 15 years after the date of the enactment of this section.

(2) This section shall continue to apply to any patent that claims a product subject to a regulatory review period, a method for using such a product, or a method of manufacturing such a product if the patent was issued before the expiration of 15 years after such date.

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CHAPTER 28—INFRINGEMENT OF PATENTS PT. III

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§ 271. Infringement of patent

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(e) * * *

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(5)(A) Except as provided in subparagraph (B), during the last 2 years of the term of a patent relating to a pesticide (including a

patent that claims a pesticide, a method for using a pesticide, or a method of manufacturing a pesticide) that is or has been registered under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) or that is marketed with the permission of the holder of such patent, it shall not be an act of infringement of such patent to make, use, or sell such pesticide solely for testing reasonably related to the development and submission of data—

(i) to meet regulatory requirements under the Federal Insecticide, Fungicide, and Rodenticide Act,

(ii) to obtain a tolerance or an exemption from a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a), or

(iii) to obtain a food additive regulation or an exemption from a food additive regulation under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348).

(B)(i) Subparagraph (A) shall apply only to the first patent issued for a pesticide, a method of using a pesticide, or a method of manufacturing a pesticide that makes the unlicensed manufacture, use, or sale of the pesticide a patent infringement.

(ii) Subparagraph (A) shall not apply to a patent that claims a method of manufacturing a pesticide that uses recombinant DNA or hybridoma technology in the manufacture of the pesticide.

(C) It shall be an act of infringement for any person to submit any application under the Federal Insecticide, Fungicide, and Rodenticide Act or section 408 or 409 of the Federal Food, Drug, and Cosmetic Act for a pesticide covered by the first composition of matter patent, method of use patent, or method of manufacturing patent issued for the pesticide if such application is submitted before the expiration of the term of such first patent unless such person is the holder of such patent or a licensee of the holder.

(D) For purposes of this paragraph, all formulations of a pesticide containing the identical active ingredient shall be considered the same pesticide.

§ 282. Presumption of validity; defenses

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In actions involving the validity or infringement of a patent the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as anticipation of the patent in suit or, except in actions in the United States Claims Court, as showing the state of the art, and the name and address of any person who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit. In the absence of such notice proof of the said matters may not be made at the trial except on such terms as the court requires. Invalidity of the extension of a patent term or any portion thereof under section 156 of this title because of the material failure—

(1) by the applicant for the extension, or

(2) by the Commissioner,

to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due diligence determination under section 156(d)(2) *or 158(e)* is not subject to review in such an action.

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TITLE 42, UNITED STATES CODE

PART C—PROTECTION OF UNDERGROAUND SOURCES OF DRINKING WATER

§ 1428. State Programs to Establish Wellhead Protection Areas

(a) STATE PROGRAMS.—The * * *

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§ 1429. Ground Water Residue Guidance Level

(a) ISSUANCE OF LEVELS.—

(1) PERMISSIVE ISSUANCE FOR REGISTERED PESTICIDES.—The Administrator, on the Administrator's own initiative, may issue a ground water residue guidance level for a pesticide registered under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.).

(2) MANDATORY ISSUANCE FOR CERTAIN PESTICIDES.—The Administrator shall issue a ground water residue guidance level for a pesticide whenever the Administrator registers or reregisters a pesticide under such Act if the Administrator determines that the pesticide has the potential to leach into ground water.

(3) MANDATORY ISSUANCE BASED ON CERTAIN DATA.—In addition, the Administrator shall issue a ground water residue guidance level for a pesticide if—

(A) based on reliable analytical data, the pesticide has been detected at ground water sampling points in three or more different geographical areas;

(B) based on reliable analytical data, the pesticide has been detected in a drinking water well or wellfield that serves a population of over 500 people; or

(C) a Federal agency or a State petitions the Administrator to set a ground water residue guidance level for the pesticide.

(b) LEVELS.—

(1) MAXIMUM CONTAMINANT LEVELS.—If the Administrator has promulgated or promulgates a maximum contaminant level under section 1412(b)(3) that applies to a pesticide the ground water residue guidance level required under subsection (a) for the pesticide shall be set at such level within 30 days of being required under such section.

(2) ESTABLISHING LEVEL IN ABSENCE OF MAXIMUM CONTAMINANT LEVEL.—

(A) USE OF HEALTH ADVISORY LEVELS.—If a maximum contaminant level that would be applicable to a pesticide for which a ground water residue guidance level is required by subsection (a) has not been established under section 1412, the Administrator, in the Administrator's discretion, may use a health advisory level in establishing such ground water residue guidance level.

(B) FACTORS FOR DETERMINING LEVEL.—The ground water residue guidance level established under this paragraph by the Administrator for such pesticide shall reflect the level of the pesticide in drinking water at which no known or anticipated adverse effect on the health of persons occur, the need for an adequate margin of safety, the nature of the toxic effects caused by the pesticide, and the validity, completeness, and adequacy of data about the pesticide.

(C) ALL ABSENT OR INVALID DATA.—If all required chronic, oncogenicity, reproduction, or teratogenicity data are absent or invalid for the pesticide, the ground water residue guidance level for the pesticide established under this paragraph shall be set at the limit of detection.

(D) CERTAIN ABSENT OR INVALID DATA.—If any required chronic, oncogenicity, reproduction, or teratogenicity data are absent or invalid for the pesticide, the ground water residue guidance level established under this paragraph for the pesticide shall include an additional margin of safety that takes into account the absence of such data.

(c) PROCEDURE.—

(1) INTERIM LEVELS FOR GENERAL PESTICIDES.—Before issuing a final ground water residue guidance level for a pesticide, the Administrator shall publish an interim ground water residue guidance level for the pesticide in the Federal Register and allow public comment for at least 30 days. During the public comment period, the Administrator shall invite comment on such level from the Secretary of Agriculture and States.

(2) INTERIM LEVELS FOR PESTICIDES WITH HEALTH ADVISORY LEVELS.—If the Administrator is required under subsection (a) to issue a ground water residue guidance level for a pesticide and the ground water residue guidance level is to be issued pursuant to subsection (b)(2), the Administrator shall issue an interim ground water residue guidance level within 30 days after the requirement to issue the ground water residue guidance level takes effect.

(3) FINAL LEVELS.—Within 3 months after establishing an interim ground water residue guidance level, the Administrator shall establish a final ground water residue guidance level. Until a final ground water residue guidance level is established under subsection (a) for a pesticide, an interim ground water residue guidance level established for the pesticide shall remain in effect.

(d) REVISION OF LEVELS.—The Administrator may revise a ground water residue guidance level for a pesticide. The Administrator shall allow at least 30 days for public comment on any proposed revisions.

(e) JUDICIAL REVIEW.—An interim ground water residue guidance level shall not be subject to judicial review before the expiration of 3 months after its issuance. Judicial review of any final ground water residue guidance level or failure to establish an interim or final ground water residue guidance level shall be governed by section 1448. A ground water residue guidance level estabished under subsection (b)(1) shall not be subject to judicial review.

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ADDITIONAL VIEWS OF SENATORS HEFLIN, COCHRAN, PRYOR, DOLE, BOND, HELMS, KARNES, McCONNELL, AND BREAUX TO S. 1516, REPORT ON NATIONAL UNIFORMITY

S. 1516, as reported from the Committee, is a complex piece of legislation. Many difficult problems have been resolved while others are left unanswered. The bill contains many provisions which, if enacted into law, will improve the Environmental Protection Agency's (EPA) ability to manage an effective pesticide program. In our judgment, however, the legislation is flawed since it does not contain the compromise uniform tolerance provision which passed the House of Representatives on October 16, 1986. We feel it is extremely important that this omission should be corrected.

The Senate Agriculture Committee bill does not contain the uniform tolerance provision which was a cornerstone of the October 16, 1986 compromise. While the Committee's effort commendably expedites both the EPA's pesticide re-registration process and the public release of scientific data, there is no requirement that the safety decisions which are made for only those chemicals which pass every modern scientific test apply across the country on a nationwide basis.

Today's lack of uniformity threatens to create chaos at the nations 350,000 supermarkets. We have a national food supply, manufacturing and distribution system. Farm commodities move freely across interstate borders. Finished food products produced, processed or manufactured in one state may serve consumers in the forty-nine other states.

The compromise uniform tolerance provision consists of three parts:

First, once a chemical has passed the new, stringent re-registration requirements, once the best scientific minds in the country have evaluated the chemical which may appear in food and declared them to be safe, then, and only then should these safety standards apply uniformly across the country.

Second, if a farmer legally used a chemical, States would be prohibited from enforcing a different standard on food unless the State determined that its residents were subjected to any "unreasonable risk to human health". States would be able to act immediately. This standard of safety was set at the request of the Chairman of the Subcommittee on Health of the House Energy and Commerce Committee, Mr. Henry Waxman.

Third, a state may file a petition with the EPA if it believes the Agency has acted improperly in deciding a health issue where "unreasonable risk to human health" exists. If EPA takes no action, the State is free to take any action it deems necessary. Indeed, the EPA may only deny a State petition if the Administrator deter-

mines that the federal level "protects, in the state of the petitioner, human health * * * "

While national uniformity was not specifically addressed in the Senate Agriculture Committee markup, we would reserve the right to address this very important matter at a later time.

HOWELL HEFLIN.
THAD COCHRAN.
DAVID PRYOR.
BOB DOLE.
KIT BOND.
JESSE HELMS.
DAVID K. KARNES.
MITCH MCCONNELL.
JOHN BREAUX.

ADDITIONAL VIEWS OF SENATOR CONRAD

The FIFRA legislation reported by the Senate Committee on Agriculture, Nutrition, and Forestry represents a significant improvement to current law. Most important are the provisions to expedite the re-registration of many agricultural chemicals that have never been fully tested for their potential effects on human health. This legislation is the product of reasonable compromises on many issues. One compromise resulted in excluding provisions dealing with the issue of pesticide tolerances on foods sold in interstate commerce.

Currently, each State may establish its own tolerance for foods marketed within its borders. To avoid potential market disruption, many farm groups and the food manufacturing industry have sought provisions promoting the concept of uniform tolerances among the States. A provision that would accomplish this purpose passed the House of Representatives in October 1986. That legislation would have precluded the States from establishing different tolerances unless a State determined that the Federal tolerance did not adequately protect human health.

Protecting their citizens' health is a responsibility that many States consider fundamental; thus, on a philosophical level, it is argued that the States should not be precluded from establishing pesticide tolerances on food that may very from Federal tolerances. However, as a practical matter, they simply shouldn't have to. By establishing a different tolerance level, a State assumes the considerable burden of monitoring shipments and testing to ensure compliance. This burden may partially explain why States have acted to impose stricter tolerances in only a few situations.

Federal responsibility for determining the safety of chemical residues on food rests with the Environmental Protection Agency. The resources and scientific expertise available to EPA, especially as augmented by the provisions of S. 1516, are likely to exceed that which any individual State can afford. Among the States, some are better able than others to make the commitment of time and resources for pesticide testing programs.

An effective Federal program, in which EPA is mandated to consider the most recent scientific data supplied by the States or by other sources, would preclude the need for separate action by the States. The provisions passed by the House of Representatives recognize the benefits of this approach. Those provisions could be strengthened, however, by requiring EPA to give greater consideration to data supplied by the States, or by requiring EPA to explain why such data do not warrant a change in the existing tolerance level. Thus, the States—particularly those with active testing programs—would be given a larger voice in determining tolerance levels, allowing the citizens of all States to benefit.

It simply does not make sense that a given level of pesticide residue is "safe" in one State, but is not "safe" for identical populations in another. Our nation's farmers need and depend on orderly marketing systems and access to nationwide markets for their products. For these reasons, provisions for promoting uniform pesticide tolerance levels, while protecting the States' ability to challenge the Federal finding, would enhance this important legislation.

KENT CONRAD.

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